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IN THE

Supreme Court of the United States

OCTOBER TERM, 1996

SMITHS INDUSTRIES MEDICAL SYSTEMS, INC.,

Petitioner,

v.

SARAH KERNATS, a minor, by CYNTHIA KERNATS, her mother and next friend, CYNTHIA KERNATS, individually, and ANDREW KERNATS,

Respondents.

SMITHS INDUSTRIES MEDICAL SYSTEMS, INC.,

Petitioner,

v.

JOYCE OSHODI, individually and as mother and next friend of KENNETH OSHODI, a minor,

Respondents.

SMITHS INDUSTRIES MEDICAL SYSTEMS, INC.,

Petitioner,

v.

MARY SUSAN WILLIAMS, as mother and next friend of JOHN CALVIN WILLIAMS, a minor,

Respondents.

On Petition for Writ of Certiorari to the Appellate Court of Illinois, First District

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PETITION FOR WRIT OF CERTIORARI

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QUESTIONS PRESENTED

1. Should this Court resolve the growing conflict among State and Federal Courts regarding the preemptive effect of the Medical Device Amendments on state law claims that challenge the safety and effectiveness of Class III medical devices approved by the United States Food and Drug Administration pursuant to the premarket approval process and/or the investigational device exemption process?

2. Do the Medical Device Amendments preempt state law claims that challenge the safety and effectiveness of Class III medical devices approved by the United States Food and Drug Administration pursuant to the premarket approval process and/or the investigational device exemption process?

RULE 29.6 STATEMENT

Petitioner, Smiths Industries Medical Systems, Inc., is a wholly-owned subsidiary of Smiths Industries, Inc. Smiths Industries, Inc. is a wholly-owned subsidiary of Smiths Industries plc.

Petitioner, Smiths Industries Medical Systems, Inc., has no nonwholly-owned subsidiaries.

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PETITION FOR WRIT OF CERTIORARI

Petitioner, Smiths Industries Medical Systems, Inc. ("SIMS"), respectfully petitions for a writ of certiorari to review the judgment of the Appellate Court of Illinois, First District.

OPINIONS BELOW

The opinion of the Appellate Court of Illinois is reported at 283 Ill. App. 3d 455, 669 N.E.2d 1300 (1st Dist. 1996). (App. at 1-19). The trial court rulings are unreported. (App. at 25, 26-31, 32).

JURISDICTIONAL STATEMENT

The Appellate Court of Illinois, First District, entered judgment on September 6, 1996. (App. at 1-19).

The Supreme Court of Illinois denied SIMS' Petition for Leave to Appeal on December 4, 1996. (App. at 20-24).

Jurisdiction of this Court arises under 28 U.S.C. §1257. In addition, review on Writ of Certiorari is warranted under Supreme Court Rule 10(b) because the Illinois Appellate Court decided an important Federal question in a way that conflicts with the decision of a United States Court of Appeals *and* another State court of last resort.

STATUTE INVOLVED

This case involves §360k(a) of the Medical Device Amendments of 1976, which provides as follows:

> (a) Except as provided in subsection (b) of this Section, no State or political subdivision of a State may establish or continue in effect with respect to a device intended for human use any requirement—
>
> (1) which is different from, or in addition to, any requirement applicable under this chapter to the device, and
>
> (2) which relates to the safety or effectiveness of the device or to any other matter included in a requirement applicable to the device under this chapter.

21 U.S.C. §360k(a) (Supp. 1992).

STATEMENT OF THE CASE

I. PROCEEDINGS BELOW

A. In The Trial Court

This Petition arises from three separate products liability actions filed against SIMS in the Circuit Court of Cook County, Illinois: *Kernats v. SIMS; Oshodi v. SIMS;* and *Williams v. SIMS*.

The allegations and undisputed facts of all three cases are nearly identical. The plaintiffs in each case consist of a mother and a child allegedly born with limb deformities. In each case, the mother underwent chorionic villus sampling ("CVS") during her pregnancy. CVS is a medical procedure performed during the first trimester of

pregnancy to obtain a sample of fetal tissue which is then analyzed for genetic abnormalities.

The plaintiffs in each case allege that SIMS manufactured and sold the CVS catheter used in the CVS procedure in controversy. The plaintiffs further allege that the CVS procedure caused the then-unborn child to be born with limb deformities. The plaintiffs seek recovery under theories of strict products liability, common law negligence, and breach of express and implied warranties.

The CVS catheter involved in all three cases is classified as a "Class III" medical device under the Medical Device Amendments of 1976 ("MDA"), 21 U.S.C. §§360c-360*l*. The MDA contains a comprehensive regulatory scheme which governs the development, marketing and distribution of all Class III medical devices. Pursuant to the MDA's regulatory scheme, certain Class III medical devices may be distributed for use only if the United States Food and Drug Administration ("FDA") grants the device (1) an Investigational Device Exemption ("IDE"), or (2) premarket approval ("PMA"). The FDA may grant a medical device an IDE or PMA only after carefully evaluating the device to ensure that it is safe and effective for its intended use. 21 C.F.R. §812.30, 21 U.S.C. §360e(d)(2).

On September 19, 1984, the FDA granted SIMS an IDE for the CVS catheter in controversy. That IDE was in effect when the CVS procedures at issue in *Oshodi* and *Williams* were performed on June 11, 1986, and October 12, 1988, respectively.

On August 9, 1990, the FDA granted SIMS premarket approval for the CVS catheter in controversy. On August

17, 1990, the FDA granted SIMS premarket approval for the warning label for the CVS catheter. The FDA's premarket approval of the CVS catheter and its warning label was in effect when the CVS procedure at issue in *Kernats* was performed (November 1, 1990) and has remained in effect through the present day.

In all three cases, SIMS moved for summary judgment on the grounds that all of the plaintiffs' claims were preempted by the express preemption provision of the MDA, 21 U.S.C. §360k(a).[1] The trial court granted SIMS' Motion for Summary Judgment in *Kernats* on November 17, 1994. (App. at 25). The trial court granted SIMS' Motion for Summary Judgment in *Oshodi* on June 22, 1995. (App. at 26-31). The trial court granted SIMS' Motion for Summary Judgment in *Williams* on June 30, 1995. (App. at 32).

B. In The Appellate Court of Illinois

The plaintiffs in all three cases appealed, and the Appellate Court consolidated the appeals based on their common facts and legal issues. On September 6, 1996, the Appellate Court reversed the judgment of the trial court in all three cases, holding that the MDA does not preempt any of the plaintiffs' claims. (App. at 1-19). The Appellate Court's decision (hereinafter "the *Kernats* decision") is reported at 283 Ill.App.3d 455, 669 N.E.2d 1300 (1st Dist. 1996).

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[1] Each of the three lawsuits was pending before a different trial court judge. All three trial judges granted SIMS' summary judgment motion.

C. Before the Supreme Court of Illinois

On October 8, 1996, SIMS timely filed a Petition for Leave to Appeal with the Supreme Court of Illinois. SIMS' Petition was denied on December 4, 1996. (App. at 20-24).

II. JUDGMENT SOUGHT TO BE REVIEWED

The Appellate Court in *Kernats* based its decision on this Court's decision in *Medtronic, Inc. v. Lohr*, 116 S.Ct. 2240 (1996). The plaintiff in *Medtronic* filed a products liability action against the manufacturer of an allegedly defective pacemaker lead. The pacemaker lead at issue in *Medtronic* was a Class III medical device. *Id.* at 2248. However, unlike the CVS catheter involved in this Petition, the pacemaker lead in *Medtronic* did *not* undergo the rigorous IDE or PMA regulatory process. *Id.* Rather, the pacemaker lead was marketed as a "substantially equivalent" medical device pursuant to the MDA's Premarket Notification process (hereinafter "the 510(k) process"). *Id.*

As will be explained in detail below, the 510(k) process subjects "substantially equivalent" Class III medical devices to only minimal review by the FDA (as compared to the rigorous IDE and PMA processes). Further, the FDA does *not* evaluate "substantially equivalent" devices for the purpose of ensuring their safety or effectiveness.

Despite the significant differences between the 510(k) process at issue in *Medtronic* and the IDE and PMA processes at issue in *Kernats*, the Appellate Court held that *Medtronic* compelled a finding that *none* of the plaintiffs' claims in *Kernats* is preempted. Specifically,

the Appellate Court held that the plaintiffs' strict liability, negligence, and breach of implied warranty claims are not preempted because those claims are based on "general obligations" applicable to all product manufacturers. (App. at 14-16). The Appellate Court further held that the plaintiffs' breach of express warranty claims are not preempted because those claims are not "imposed under State law", but rather are imposed by virtue of SIMS' own representations. (App. at 18).

REASONS FOR GRANTING THE WRIT

I.

BY GRANTING SIMS' WRIT, THIS COURT CAN CONCLUSIVELY RESOLVE THE GROWING CONFLICT THAT HAS ARISEN AMONG STATE AND FEDERAL COURTS IN CASES INVOLVING CLASS III MEDICAL DEVICES GRANTED INVESTIGATIONAL DEVICE EXEMPTIONS AND PREMARKET APPROVAL.

SIMS' Petition for Writ of Certiorari offers this Court the opportunity to resolve in *one decision* the two critical issues of MDA preemption that were not addressed in *Medtronic v. Lohr*.

A. *Medtronic v. Lohr* did not define the preemptive effect of the MDA in cases involving IDE and PMA Class III medical devices.

This Court's decision in *Medtronic* squarely addressed the scope of MDA preemption as it relates to "substantially equivalent" Class III medical devices marketed pursuant to the 510(k) process. Relying on this Court's decision in *Medtronic*, recent decisions involving 510(k) devices have reached consistent results, holding that the

MDA does not preempt state law causes of action brought against the manufacturers of such devices. See, *Duvall v. Bristol-Myers-Squibb Co.*, 103 F.3d 324 (4th Cir. Dec. 18, 1996); *Dutton v. Acromed Corp.*, 1997 WL 15248 (Ohio App. Ct. January 16, 1997); *Reeves v. Acromed Corp.*, 103 F.3d 442 (5th Cir. January 20, 1997).

However, this Court's decision in *Medtronic* did not address the preemptive effect of the MDA as it relates to IDE and PMA Class III devices. For the purposes of MDA preemption, the differences between the 510(k) process and the IDE and PMA processes are significant.[2] As a result of those differences, the lower courts—including the Illinois Appellate Court in *Kernats*—have reached conflicting results in their attempts to apply the *Medtronic* decision to cases involving IDE and PMA Class III devices.

B. In the wake of *Medtronic*, State and Federal Courts have reached conflicting results in cases involving IDE and PMA Class III devices.

As stated previously, the *Kernats* decision was a consolidated appeal involving three separate lawsuits: *Kernats*, *Oshodi* and *Williams*. At the time the CVS procedure was performed on the Plaintiffs in *Oshodi* and *Williams*, the CVS catheter had been granted an IDE. At the time the CVS procedure was performed on the Plaintiff in *Kernats*, the CVS catheter had been granted PMA.

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[2] The differences between the 510(k) process and the IDE and PMA processes will be discussed in the following section of this petition.

Thus, the *Kernats* consolidated appeal (which is the subject of this Petition) involved questions regarding the preemptive effect of the MDA on (1) a Class III device granted an IDE, *and* (2) a Class III device granted PMA. The Illinois Appellate Court resolved those questions by holding that the plaintiffs' claims in all three underlying lawsuits survived preemption.

1) Conflicts in cases involving IDE Class III devices.

The *Kernats* decision—as it relates to IDE Class III devices—directly conflicts with the recent decision of the United States Court of Appeals for the Sixth Circuit in *Martin v. Telectronics Pacing Systems, Inc.*, ___ F.3d ___, 1997 WL 35041 (6th Cir. January 31 1997).[3] *Martin* involved a Class III pacemaker that had been granted an IDE by the FDA. 1997 WL 35041 at *8. As in *Kernats*, the plaintiffs' claims against the defendant-manufacturer in *Martin* were based on defective manufacturing, defective design, inadequate warnings and breach of warranties. *Id.* at *1.

In direct conflict with the Illinois Appellate Court's decision in *Kernats*, the Sixth Circuit in *Martin* (1) distinguished *Medtronic* based on the differences between the 510(k) process and the IDE process, and (2) held that *all* of the plaintiffs' claims were preempted.

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[3] The conflict between the Illinois Appellate Court in *Kernats* and the Sixth Circuit in *Martin* brings the *Kernats* decision within this Court's jurisdiction on Writ of Certiorari under United States Supreme Court Rule 10(b).

The Sixth Circuit's decision in *Martin* also creates *another* conflict between a United States Court of Appeals and a State Court of last resort. S.Ct. Rule 10(b). The Sixth Circuit's decision in *Martin* directly conflicts with the decision of the Supreme Court of Missouri in *Connelly v. Iolab Corporation*, 927 S.W.2d 848, 853-54 (Mo. 1996) (holding that, pursuant to *Medtronic*, the MDA does not preempt claims based on negligence, strict liability, and failure to warn in a case involving IDE Class III device).

2) Conflicts in cases involving PMA Class III devices.

The *Kernats* decision—as it relates to PMA Class III devices—directly conflicts with the decision of the Supreme Court of Pennsylvania in *Green v. Dolsky*, 685 A.2d 110 (Pa. November 22, 1996).[4] *Green* involved a Class III cosmetic implant device that had been granted PMA by the FDA. *Id.* at 113,17. The plaintiff asserted numerous claims based on negligence, strict products liability, and breach of warranty. *Id.* at 117-18. The court in *Green* held that this Court's decision in *Medtronic* provided "some guidance", but *further held that Medtronic was "not wholly applicable" because of the differences between the PMA process and the 510(k) process. Id.* at 117.

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[4] The conflict between the Illinois Appellate Court in *Kernats* and the Pennsylvania Supreme Court in *Green also* brings the *Kernats* decision within this Court's jurisdiction on Writ of Certiorari under United States Supreme Court Rule 10(b).

In direct conflict with the Illinois Appellate Court in *Kernats*, the court in *Green* held that the MDA preempted the plaintiff's strict products liability, negligence[5], and breach of warranty claims. *Id.* at 117-18.

The decision of the Supreme Court of Pennsylvania in *Green* also conflicts with *Armstrong v. Optical Radiation Corporation*, 57 Cal.Rptr.2d 763 (Cal. Ct. App. October 29, 1996), and *Walker v. Johnson & Johnson Vision Products, Inc.*, 217 Mich. App. 705 (July 26, 1996), both of which held that MDA preemption does not apply to claims brought against manufacturers of Class III PMA devices.

C. Unless this Court renders a conclusive decision, the lower courts will continue to enter conflicting judgments regarding MDA preemption.

Absent a conclusive decision from this Court, the lower courts will continue to enter conflicting judgments in cases involving PMA and IDE Class III devices. As a result, this Court will continue to receive petitions for writs of certiorari in such cases.

The instant Petition submitted to this Court by SIMS is unique. Because this Petition involves questions regarding PMA *and* IDE Class III devices, this Court has the opportunity to conclusively resolve in one decision all remaining aspects of MDA preemption not addressed in *Medtronic v. Lohr*. For that reason, this Court should grant the instant Petition.

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[5] The court held that preemption did not apply to certain of the plaintiff's negligence claims which simply "mirrored" the federal requirements of the PMA process.

II.

OVERVIEW OF THE MEDICAL DEVICE AMENDMENTS OF 1976.

An overview of the MDA, as well as the different regulatory processes applicable to Class III medical devices, is crucial to an understanding of why the lower courts have been unable to consistently apply *Medtronic* to cases involving IDE and PMA Class III devices.

A. Classification of Medical Devices Under the MDA

Pursuant to the MDA, the FDA groups all medical devices into three classifications based on the degree of regulation necessary to assure the safety and effectiveness of each device. See 21 U.S.C. §360c; H.R. Conf. Rep. No. 1090, 94th Cong., 2d Sess. 55 (1976), reprinted in 1976 U.S.C.C.A.N. 1103, 1107. Class I devices, such as crutches and tongue depressors, pose little or no threat to health and are subject only to general controls. 21 U.S.C. §360c(a)(1)(A). Class II devices, such as tampons and knee prostheses, involve a slightly greater risk to health and are subject to special controls such as performance standards and post-market surveillance. 21 U.S.C. §360c(a)(1)(B).

Class III devices, such as the CVS catheter in controversy, are those which present a "potential unreasonable risk of illness or injury" and therefore require the utmost scrutiny by the FDA. 21 U.S.C. §360c(a)(1)(C)(ii)(II). Class III medical devices may be distributed for use pursuant to three different regulatory schemes: (1) premarket approval, (2) investigational device exemptions, and (3) the 510(k) process.

B. Premarket Approval

The premarket approval process is the most exhaustive regulatory scheme imposed by the FDA under the MDA. To obtain premarket approval of a Class III device, the manufacturer or distributor of the device must submit a detailed application to the FDA. 21 U.S.C. § 360e(c)(1). The application must include (1) detailed reports of all investigations and studies concerning the safety and effectiveness of the device, (2) a full statement of the components, composition and principles of operation of the device, (3) a full description of the methods, facilities and controls used for the manufacture of the device, (4) samples of the device for examination and testing, and (5) copies of the proposed labeling for the device. 21 U.S.C. § 360e(c)(1).

The FDA refers each premarket approval application to an advisory panel of specially appointed independent scientists who then review the application and prepare a report and recommendation to the FDA. 21 U.S.C. §§ 360e(c)(2), 360c(b). The FDA may approve an application for premarket approval only if it determines that the device is reasonably safe and effective for its intended use. 21 U.S.C. § 360e(d)(2). A manufacturer or distributor is subject to criminal and civil penalties for marketing or selling a Class III medical device without first obtaining FDA premarket approval. 21 U.S.C. §§ 331(p), 333(a) (Supp. 1992).

Once a Class III medical device receives premarket approval, the FDA may withdraw the approval if it subsequently determines that the device is unsafe. 21 U.S.C. § 360e(e). To enable the FDA to monitor the safety of an approved device, the manufacturer or distributor

must maintain records and submit product safety reports to the FDA. 21 U.S.C. § 360i(a)(1). A manufacturer or distributor is subject to criminal and civil penalties for failing to comply with these continuous reporting and record-keeping requirements. 21 U.S.C. §§ 331(e), 333(a) (Supp. 1992).

C. Investigational Device Exemptions

In enacting the MDA, Congress recognized that certain experimental Class III medical devices cannot be proven safe and effective—and therefore obtain premarket approval—without the benefit of preliminary clinical studies. Therefore, the MDA specifically provides for Investigational Device Exemptions ("IDEs"). 21 U.S.C. §§ 360e(a), 360j(g). IDEs permit qualified experts to investigate the safety and effectiveness of Class III devices by conducting clinical tests on human subjects before such devices have received premarket approval. 21 U.S.C. §§ 360e(a), 360j(g). Congress announced the purpose of IDEs as follows:

> It is the purpose of this subsection to encourage, to the extent consistent with the protection of the public health and safety and with ethical standards, the discovery and development of useful devices intended for human use and to that end to maintain optimum freedom for scientific investigators in their pursuit of that purpose.

21 U.S.C. § 360j(g)(1).

Although Class III devices receiving IDEs are exempt from the premarket approval process, such devices are nonetheless subject to extensive regulatory requirements promulgated and enforced by the FDA. 21 U.S.C.

§ 360j(g)(3); 21 C.F.R. §§ 812.1-150. To obtain an IDE, the sponsor of a proposed clinical investigation must complete a detailed application containing (1) a description of the device specifying its design as well as the methods, controls and facilities used for its manufacture; (2) copies of all labeling for the device; (3) the proposed plan for investigating the use of the device in human subjects; (4) written procedures for monitoring the investigation; and (5) complete reports of all prior investigations of the device. 21 U.S.C. §§ 360j(g)(2)-(3); 21 C.F.R. §§ 812.20-27.

The FDA and an institutional review committee must then review the application. 21 U.S.C. § 360j(g)(3)(a); 21 C.F.R. §§ 812.42. The FDA must reject the application if it determines there is reason to believe the investigation is scientifically unsound, the risks outweigh the anticipated benefits, or the device is ineffective. 21 C.F.R. § 812.30.

If the FDA grants a medical device an IDE, the sponsor must continuously monitor the investigation, maintain records and provide the FDA with reports describing the results of the investigation. 21 U.S.C. § 360j(g)(2)(B)(ii); 21 C.F.R. §§ 812.46; 812.140; 812.150. In addition, the sponsor must allow the FDA to inspect the investigation and manufacturing facilities and all records pertaining to the investigation. 21 C.F.R. § 812.46. The FDA must withdraw an IDE if it determines that a continuation of the clinical investigation will result in an unreasonable risk to the public health. 21 U.S.C. § 360j(g)(5). Any person who fails to comply with the requirements applicable to IDEs is subject to substantial criminal and civil penalties. 21 U.S.C. § 331(q)(1), § 333(a) (Supp. 1992).

D. The 510(k) Process

As this Court explained in *Medtronic*, a Class III medical device may bypass the IDE and PMA processes if the FDA determines that the device is "substantially equivalent" to a medical device marketed before the MDA became effective in 1976. 116 S.Ct. at 2247. A manufacturer of a Class III device may seek a finding of substantial equivalence from the FDA by participating in the 510(k) Notification Process. *Id.*

In *Medtronic*, this Court repeatedly emphasized the cursory nature of the 510(k) process. This Court explained that the 510(k) process is completed in an average of only 20 hours (as opposed to the 1,200 hours ordinarily involved in the PMA process). *Id.* This Court also emphasized that "the 510(k) process is focused on equivalence, not safety." *Id.* at 2254. In that regard, the Court quoted one commentator as follows:

> Substantial equivalence determinations provide little protection to the public. These determinations simply compare a post-1976 device to a pre-1976 device to ascertain whether the later device is no more dangerous and no less effective than the earlier device. If the earlier device poses a severe risk or is ineffective, then the later device may also be risky or ineffective.

Id. (quoting Adler, 43 Food Drug Cosm. A.J., at 516). Elaborating further, this Court observed that the only requirements imposed under the 510(k) process constitute—

> Entirely generic concerns about device regulation generally, not the sort of concerns regarding a specific device or field of device regulation which the statute or regulations were designed to pro-

tect from potentially contradictory state requirements.

Id. at 2258.

III.

THIS COURT BASED ITS FINDING OF NO PREEMPTION IN *MEDTRONIC* ON THE NATURE AND PURPOSE OF THE 510(K) PROCESS.

The MDA's express preemption provision, 21 U.S.C. §360k(a), provides as follows:

> (a) Except as provided in subsection (b) of this section, no State or political subdivision of a State may establish or continue in effect with respect to a device intended for human use any requirement—
>
> (1) which is different from, or in addition to, any requirement applicable under this chapter to the device, and
>
> (2) which relates to the safety or effectiveness of the device or to any other matter included in a requirement applicable to the device under this chapter.

21 U.S.C. § 360k(a) (Supp. 1992).

In *Medtronic*, this Court held that preemption occurs only when a medical device is subject to "specific" federal requirements. 116 S.Ct. at 2257. This Court also held that preemption applies only to state law requirements developed "with respect to" medical devices, as opposed to state requirements of "general applicability". *Id.* However, this Court acknowledged that "general" state requirements are not necessarily excluded from the scope of preemption. *Id.* Rather, preemption will occur when a

"general" state requirement "threatens to interfere with a specific federal interest". *Id.*

Based upon the foregoing guidelines for preemption, this court held that the plaintiffs' claims in *Medtronic* were not preempted for two reasons. First, the 510(k) process at issue in *Medtronic* did not impose "specific" federal requirements on the pacemaker lead in controversy. *Id.* at 2258. Second, this Court held that the plaintiffs' claims of negligence and strict products liability constituted "general" state law requirements which—

> are not the kinds of requirements that Congress and the FDA feared would impede the ability of federal regulators to implement and enforce specific federal requirements. *Id.*

Critical to this Court's decision in *Medtronic* was its discussion of the underlying purpose of the 510(k) process. This Court explained that by permitting the manufacturers of "substantially equivalent" devices to bypass the PMA process, Congress intended merely to enable those manufacturers to compete on an equal basis with the manufacturers of medical devices that existed before the MDA was enacted. *Id.* at 2254. In that regard, this Court held as follows:

> There is no suggestion in either the statutory scheme or the legislative history that the 510(k) exemption process was intended to do anything other than maintain the status quo with respect to the marketing of existing medical devices and their substantial equivalents. That status quo included the possibility that the manufacturer of the device would have to defend itself against state law claims of negligent design.

Id. at 2254-55. Since Congress did not intend to afford "substantially equivalent" device manufacturers preferential treatment, this Court held that the imposition of state law claims such as those asserted by the plaintiffs in *Medtronic* did not threaten the specific federal interest underlying the 510(k) process. *Id.*

IV.

THE PREEMPTION ANALYSIS ESTABLISHED IN *MEDTRONIC* COMPELS A FINDING IN FAVOR OF PREEMPTION IN CASES INVOLVING IDE AND PMA CLASS III MEDICAL DEVICES.

Although this Court ruled against preemption in *Medtronic*, the preemption analysis established in that case strongly suggests that a different result is warranted in cases involving IDE and PMA Class III devices.

A. The comprehensive and detailed nature of the IDE and PMA processes militate in favor of preemption.

As demonstrated earlier in this Petition, the IDE and PMA processes (as opposed to the 510(k) process) involve a comprehensive array of "specific" federal requirements. In cases decided before and after *Medtronic*, including the *Kernats* decision at issue in this Petition, the courts have consistently held that the requirements of the IDE and PMA processes are sufficiently specific to trigger preemption. See, e.g., *Kernats v. Smiths Industries Medical Systems, Inc.*, 283 Ill.App.3d 455, 669 N.E.2d 1300, 1308 (1st Dist. 1996) (PMA requirements sufficiently specific); *Martin v. Telectronics Pacing Systems, Inc.*, ___ F.3d ___, 1997 WL 35041 (6th Cir. January 31

1997) (IDE requirements sufficiently specific); *King v. Collagen Corp.*, 983 F.2d 1130, 1134 (1st Cir. 1993) (PMA requirements sufficiently specific); *Slater v. Optical Radiation Corp.*, 961 F.2d 1330, 1333 (7th Cir. 1992) (IDE requirements sufficiently specific). Thus, the requirements of the IDE and PMA processes, unlike the "generic" requirements of the 510(k) process, are sufficiently specific to satisfy the *Medtronic* preemption guidelines.

B. The Congressional goals underlying the IDE and PMA processes require that such devices be afforded the protection of MDA preemption.

The Congressional purposes of the IDE and PMA processes also differ dramatically from the purpose of the 510(k) process. Congress announced the purpose of IDEs as follows:

> It is the purpose of this subsection to encourage, to the extent consistent with the protection of the public health and safety and with ethical standards, the discovery and development of useful devices intended for human use and to that end to maintain optimum freedom for scientific investigators in their pursuit of that purpose.

21 U.S.C. § 360j(g)(1). Similarly, the PMA process is intended to ensure the safety and effectiveness of medical devices designed "for a use in sustaining human life or for a use which is of substantial importance in preventing impairment of human health". 21 U.S.C. §360c(a)(1)(C).

Unlike the 510(k) process, the IDE and PMA processes are not intended merely to facilitate the marketing of "substantially equivalent" devices that duplicate the

benefits of devices already in existence. To the contrary, Congress enacted the IDE and PMA processes to encourage the development of innovative, substantially important medical devices, and to provide the FDA with the authority and means to evaluate the safety and effectiveness of such devices. As set forth below, the preemption of state tort law claims is crucial to the achievement of those congressional objectives.

Without question, the threat of widespread tort litigation constitutes a formidable deterrent to the development of innovative, potentially life-saving medical devices. In 1988 a report of the American Medical Association ("AMA") Board of Trustees concluded that "[p]roduct liability is having a profound negative impact on the development of new medical technologies."[6] The AMA report explained that "[i]nnovative new products are not being developed or are being withheld from the market because of liability concerns or inability to obtain adequate insurance".[7]

The threat of widespread tort litigation has a particularly chilling effect on smaller manufacturers which, although often responsible for developing the most innovative medical devices, have less financial resources at their disposal. Absent any protection from MDA preemption, such smaller manufacturers will be compelled to cease the development of potentially life-saving medical devices—or withdraw such devices from the market—rather than face the threat of devastating litigation

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[6] AMA, Report of the Board of Trustees: Impact of Product Liability on the Development of New Medical Technologies 1 (June 1988).

[7] *Id.*

defense costs. Such a result will severely undermine Congress' goal of promoting the advancement of medical device technology, and will also jeopardize the interests of countless patients whose very lives may depend on the continued availability of innovative medical devices.

The CVS catheter at issue in this Petition demonstrates the kind of significant social value innovative IDE and PMA Class III devices may offer. CVS enables physicians to perform prenatal genetic testing at an earlier stage than pre-existing procedures such as amniocentesis. The early diagnosis of fetal abnormalities attainable through CVS aids the decision making process of parents and may enable physicians to correct such abnormalities. CVS has been performed safely on thousands of patients[8], and criticisms of the procedure have largely focused on the timing of the procedure rather than the design of the SIMS catheter. Nonetheless, absent MDA preemption, SIMS and similar medical device manufacturers, despite having received FDA approval, must defend themselves in litigation such as the underlying lawsuits.

In *Slater v. Optical Radiation Corp.*, 961 F.2d 1330 (7th Cir. 1992), a case involving an IDE Class III device, the United States Court of Appeals for the Seventh Circuit explicitly recognized the chilling effect tort liability may have on the advancement of medical device technology. There, the Seventh Circuit held in relevant part as follows:

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[8] Jackson, et al., A Randomized Comparison of Transcervical and Transabdominal Chorionic Villus Sampling, New England Journal of Medicine, Vol. 327, No. 9 at 594.

> If experimental procedures are subject to hindsight evaluation by juries, so that failed experiments threaten to impose enormous tort liability on the experimenter, there will be fewer experimental treatments, and patients will suffer.

Id. at 1334. In furtherance of Congress' goal to promote the advancement of medical device technology, the Seventh Circuit in *Slater* held that the MDA preempted all of the state law tort claims the plaintiff had brought against the manufacturer of an IDE Class III device. *Id.* at 1334.

More recently, in *Martin v. Telectronics Pacing Systems, Inc.*, ___ F.3d ___, 1997 WL 35041 (6th Cir. January 31 1997), the United States Court of Appeals for the Sixth Circuit held that the structure and purpose of the IDE process *demands* the preemption of state tort law claims. *Martin* involved a Class III pacemaker that had been granted an IDE by the FDA. *Id.* at *8. The court in *Martin* noted that IDE devices (1) are subject to a specific set of "comprehensive regulations which set forth detailed procedures for determining whether investigational devices are safe and effective," and (2) are expressly *exempted* from the "performance standards" and "good manufacturing practices" normally applicable to other, non-investigational devices. *Id.* at *5-6.

Turning to the plaintiffs' claim for defective manufacturing, the court held as follows:

> The purpose of the exemption for investigational devices is to promote safety and innovation, the twin aims of the investigational device exemption of the MDA. *To allow a cause of action for a manufacturing defect under state law where the FDA has specifically exempted an investigational*

> *device from Good Manufacturing regulations would thwart the goals of the IDE exemption "to encourage, to the extent consistent with the protection of public health and safety and with ethical standards, the discovery and development of useful devices intended for human use."* 21 U.S.C. § 360j(g). We, therefore, hold that the Martins' manufacturing defect cause of action is preempted.

Id. at *9 (emphasis added). With respect to the plaintiffs' defective design claim, the court held as follows:

> To allow a cause of action for design defect where the FDA has specifically approved of the design of the device for investigational purposes would thwart the goals of safety and innovation. Accordingly, Count II of Plaintiffs' complaint is similarly preempted.

Id. at *10.

As the Sixth Circuit recognized in *Martin*, in order to "maintain optimum freedom for scientific investigators", 21 U.S.C. § 360j(g)(1), the IDE process exempts investigational devices from those federal requirements ordinarily applicable to all other devices. By permitting *state* requirements to stand where even *federal* requirements are prohibited, the allowance of state law tort claims against investigational devices totally conflicts with the structure of the IDE process, and seriously threatens the freedom of device manufacturers to pursue the development of potentially life-saving medical devices. Similarly, by allowing juries to second-guess the FDA and evaluate the safety and effectiveness of devices *already deemed safe and effective by the FDA*, state tort law claims directly undermine the federal interest in entrusting

such evaluations to the FDA. For those reasons, such claims should not be allowed to survive preemption.

V.

ADDITIONAL CONSIDERATIONS UNDERLYING THIS COURT'S DECISION IN *MEDTRONIC* STRONGLY SUGGEST THAT PREEMPTION IS WARRANTED IN CASES INVOLVING IDE AND PMA CLASS III MEDICAL DEVICES.

A. Unlike "substantially equivalent" Class III medical devices, IDE and PMA Class III medical devices are comprehensively examined by the FDA to ensure their safety and effectiveness, and comprise only a small percentage of all medical devices distributed to the public.

This Court repeatedly emphasized in *Medtronic* that "substantially equivalent" Class III devices marketed pursuant to the 510(k) process are not evaluated for safety or effectiveness. This court observed that "the 510(k) process is focused on equivalence, not safety." 116 S.Ct. at 2254. This Court also noted that the 510(k) process "requires little information, rarely elicits a negative response from the FDA, and gets processed very quickly." *Id.* at 2247. Finally, this Court explained that the 510(k) review process is completed in an average of *only 20 hours. Id.*

In *Medtronic*, this Court also explained that the vast majority of Class III medical devices introduced after 1976 have been marketed pursuant to the 510(k) process. This Court noted that a 1983 House Report "concluded that nearly 1,000 of approximately 1,100 Class III devices that had been introduced to the market since 1976 were admitted as substantial equivalents and without

any PMA review." 116 S.Ct. at 2247. This Court also cited a 1990 House Report that showed that 80% of new Class III devices were being introduced to the market through the 510(k) process and without PMA review. *Id.* at 2248.

The foregoing considerations undoubtedly played a significant role in this Court's finding of no preemption in *Medtronic*. A contrary holding in favor of preemption would have provided total immunity to the manufacturers of Class III medical devices that have never been specifically reviewed for safety or effectiveness. The error of such a result would have been compounded by (1) the sheer number of Class III medical devices introduced to market through the 510(k) process, and (2) the fact that Class III medical devices, by definition, are those which present a "potential unreasonable risk of illness or injury". 21 U.S.C. §360c(a)(1)(C)(ii)(II). Thus, for obvious reasons, the Supreme Court preserved common law tort remedies with respect to a particularly large subclass of potentially dangerous, minimally regulated, medical devices.

The considerations that disfavored preemption in *Medtronic* do not apply to cases involving IDE and PMA Class III medical devices. As demonstrated above, IDE and PMA Class III devices are comprehensively examined by the FDA to ensure their safety and effectiveness. In fact, this Court in *Medtronic* highlighted the fact that the FDA devotes an average of 1,200 hours to each PMA application (as opposed to the mere 20 hours involved in the 510(k) process). *Id.* at 2247. The IDE process involves the same kind of rigorous FDA review. Furthermore, in contrast to 510(k) devices, IDE and PMA Class

III devices comprise a small fraction of the total medical devices distributed to the public.

Thus, unlike a finding of preemption with respect to 510(k) devices, a finding of preemption with respect to IDE and PMA Class III devices would apply only to a small number of intensely regulated medical devices.

B. In *Medtronic*, a majority of this Court's Justices held that the MDA will preempt state law tort claims under appropriate circumstances.

In *Medtronic*, Justice Stevens wrote that "few, if any, common-law duties have been pre-empted by" the MDA. 116 S.Ct. at 2259. A majority of Justices, however, disagreed with that conclusion. Justice Breyer specifically declined to join that aspect of Justice Stevens' opinion, holding that "I am not convinced that future incidents of MDA pre-emption of common-law duties will be 'few' or 'rare'". *Id.* at 2262. In addition, Justice O'Connor (joined by Justices Rehnquist, Scalia and Thomas) expressly concluded that common-law claims are subject to pre-emption by the MDA. *Id.* at 2263.

Thus, the critical—yet unanswered—question involves the circumstances under which the MDA will preempt common-law tort claims such as those at issue in this Petition. The answer must be that preemption is appropriate in cases involving IDE and PMA Class III devices. No other devices are subject to the same degree of specific federal requirements relating to safety and effectiveness. No other devices are subject to a regulatory scheme specifically intended to promote the advancements of medical device technology. In short, no other devices are

more deserving of the protection afforded by the MDA's express preemption provision.

For those reasons, this Court's decision in *Medtronic* appears to lead to the inescapable conclusion that MDA preemption applies to common-law claims that challenge the safety and effectiveness of IDE and PMA Class III devices.

In conclusion, several aspects of this Court's decision *Medtronic* strongly suggest that the MDA preemption should be invoked in cases involving IDE and PMA Class III devices. As a result, courts such as the Sixth Circuit in *Martin v. Telectronics* and the Pennsylvania Supreme Court in *Green v. Dolsky* have held in favor of preemption. However, due to the perceived uncertainties regarding this Court's decision in *Medtronic*, other courts such as the Illinois Appellate Court in *Kernats* and the Missouri Supreme Court in *Connelly v. Iolab* have held against preemption.

There is no reason to believe that the growing conflict among the lower courts will resolve itself. The intervention of this Court is the only feasible solution. By accepting the instant Petition, this Court can conclusively resolve *in one decision* the critically important issues regarding MDA preemption as it relates to IDE Class III devices and PMA Class III devices. SIMS' petition for writ of certiorari should be granted.

CONCLUSION

The petition for writ of certiorari should be granted.

Respectfully submitted,

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APPENDIX

No. 94-4386 (Consolidated with 95-3128 and 95-3129)

IN THE APPELLATE COURT OF ILLINOIS
FIRST JUDICIAL DISTRICT—SECOND DIVISION

SARAH KERNATS, et al.,	)	
	)	On Appeal from the
Plaintiffs-Appellants,	)	Circuit Court of Cook
	)	County, Law Division
v.	)	No. 91 L 13573
	)	
SMITHS INDUSTRIES MEDICAL SYSTEMS, INC.,	)	Honorable
	)	Joseph N. Casciato,
	)	Judge Presiding
Defendant-Appellee.	)	
	)	
JOYCE OSHODI, et al.,	)	
	)	On Appeal from the
Plaintiffs-Appellants,	)	Circuit Court of Cook
	)	County, Law Division
v.	)	No. 94 L 7177
	)	
SMITHS INDUSTRIES MEDICAL SYSTEMS, INC.,	)	Honorable
	)	Robert V. Boharic,
	)	Judge Presiding
Defendant-Appellee.	)	
	)	
MARY SUSAN WILLIAMS, et al.,	)	
	)	On Appeal from the
Plaintiffs-Appellants,	)	Circuit Court of Cook
	)	County, Law Division
v.	)	No. 93 L 015781
	)	
SMITHS INDUSTRIES MEDICAL SYSTEMS, INC.,	)	Honorable Jennifer
	)	Duncan-Brice,
	)	Judge Presiding
Defendant-Appellee.	)	

Decided September 3, 1996

Presiding Justice HARTMAN delivered the opinion of the court:

This action involves three consolidated appeals. Plaintiffs in all three cases filed suit against defendant Smith Industries Medical Systems, Inc., d/b/a Concord/Portex, Inc., to recover damages for injuries allegedly caused by a medical product that it manufactured, distributed, and sold. In all cases, the circuit court entered summary judgment in favor of defendant on the ground that plaintiffs' claims were preempted by the Medical Device Amendments of 1976 (the "MDA") (21 U.S.C. §§ 360c-3601 (1988)) to the Federal Food, Drug, and Cosmetic Act (21 U.S.C. §§ 301-395 (1988)). Plaintiffs in all three cases appeal those judgments.[1]

Following oral argument in this appeal, the parties successfully moved that this court await the ruling of the United States Supreme Court in *Medtronic, Inc. v. Lohr,* 518 U.S. ___, 116 S.Ct. 2240, 135 L.Ed.2d 700 (1996) (*Medtronic*), which involved issues similar to those presented in this case: whether plaintiffs' state law tort claims are preempted by the MDA.

The allegations and undisputed facts in all three cases are essentially the same. In each case, the mother underwent chorionic villus sampling ("CVS") during her pregnancy. CVS is a medical procedure performed during

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[1] Plaintiff Mary Susan Williams, as mother and next friend of John Calvin Williams, a minor, also appealed from orders dismissing defendants Illinois Masonic Medical Center and Alan Cadkin, M.D. On January 31, 1996, this court entered an order allowing the partial dismissal of these defendants because the issues in their appeal did not relate to the preemption question common to the other consolidated cases.

the first trimester of pregnancy to obtain a sample of fetal tissue which is subsequently analyzed by geneticists for genetic abnormalities. Defendant manufactured, distributed, and sold the CVS catheter used in each CVS procedure. Plaintiffs allege that the CVS procedure caused the minors to be born with limb abnormalities.

Plaintiffs in all three appeals asserted identical theories of liability: (1) strict products liability based on the allegedly defective design and manufacture of the CVS catheter, failure to warn, and inadequate instructions; (2) breach of express and implied warranties; and (3) common law negligence based on failure to warn, inadequate testing, and negligent design of the CVS catheter.[2]

The CVS catheters involved received Food and Drug Administration (FDA) premarket approval on August 9, 1990. The catheter is used in obtaining chorionic tissue samples making possible prenatal diagnosis of genetic abnormalities. 55 Fed.Reg. 42779 (1990). On August 17, 1990, the FDA granted defendant additional premarket approval for the warning label on the CVS catheter.

Defendant successfully moved for summary judgment in all three cases, based upon asserted MDA preemption of plaintiffs' state law claims. The circuit courts found no just reason to delay enforcement or appeal of the orders pursuant to Supreme Court Rule 304(a) (155 Ill.2d

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[2] Those provisions of the Civil Justice Reform Amendments of 1995 relating to product liability actions are inapplicable to this case because they apply only to causes of action filed on or after March 9, 1995. Pub.Act. 89-7, § 15, eff. March 9, 1995. Each of the three consolidated actions involved here was filed prior to the effective date of the amendments.

R.304(a)). Plaintiffs timely filed notices of appeal from those respective orders. We consolidated the cases for purposes of appeal.

I

Summary judgment properly may be entered if the pleadings, exhibits, affidavits and depositions on file disclose no genuine issue of material fact entitling the movant to judgment as a matter of law. *Dudek, Inc. v. Shred Pax Corp.*, 254 Ill.App.3d 862, 868, 193 Ill.Dec. 653, 626 N.E.2d 1204 (1993); *Bernard v. Sears, Roebuck & Co.*, 166 Ill.App.3d 533, 534, 116 Ill.Dec. 945, 519 N.E.2d 1160 (1988). The principal issue, that of preemption, is a question of law which will be examined under a de novo standard of review. *Zoeller v. Augustine*, 271 Ill.App.3d 370, 374, 208 Ill.Dec. 17, 648 N.E.2d 939 (1995); *American Health Care Providers, Inc. v. County of Cook*, 265 Ill.App.3d 919, 923, 202 Ill.Dec. 904, 638 N.E.2d 772 (1994).

The MDA comprehensively regulates medical devices. The FDA is authorized to classify medical devices intended for human use into three categories based on the degree of regulation necessary to assure safety and effectiveness. See 21 U.S.C. § 360c. See generally *Medtronic*, 518 U.S. at ___, 116 S.Ct. at 2246

Class I devices, such as tongue depressors, are subject only to general controls on manufacturing processes because they pose little threat to public health and safety. 21 U.S.C. § 360c(a)(1)(A); *Stamps v. Collagen Corp.*, 984 F.2d 1416, 1418 (5th Cir.1993). Class II devices, such as bone-conduction hearing aids, for which "general controls by themselves are insufficient to provide reasonable as-

surance of the safety and effectiveness of the device," are subject to special controls. 21 U.S.C. § 360c(a)(1)(B); 21 C.F.R. § 874.3300 (1995). Class III devices, applying to the CVS catheter in this case, present "a potential unreasonable risk of illness or injury," and are subject to the most stringent MDA controls. 21 U.S.C. § 360c(a)(1)(C).

In order to market a Class III device, a manufacturer must provide the FDA with a "reasonable assurance" that the device is both safe and effective. *Medtronic,* 518 U.S. at ___, 116 S.Ct. at 2246, citing 21 U.S.C. § 360e(d)(2). This is accomplished by obtaining premarket approval (PMA), a rigorous process that requires manufacturers to submit to the FDA detailed information regarding the safety and efficacy of their medical devices. *Medtronic,* 518 U.S. at ___ - ___, 116 S.Ct. at 2246-47.

As part of the PMA application for a Class III device, a manufacturer must submit a bibliography of all reports concerning the device's safety and effectiveness, an outline of the device's components and properties, a description of the manufacturing process, safety data, samples of the device, copies of all proposed labeling, and any other information the FDA requests. 21 U.S.C. § 360e(c)(1). See also 21 C.F.R. § 814.20 (1995). The application is referred to a panel of qualified experts for study and submission of a report and recommendation respecting approval. 21 U.S.C. § 360e(c)(2). The FDA retains the right to withdraw its approval if it finds that a device previously approved is unsafe or ineffective. 21 U.S.C. § 360e(e).

Two important exceptions to the PMA requirement allow Class III devices to reach the marketplace without

PMA review. First, a grandfather provision allows pre-1976 medical devices to remain on the market until such time as the FDA initiates and completes the requisite PMA. See 21 U.S.C. § 360e(b)(1)(A); 21 C.F.R. § 814.1(c)(1) (1995). Second, the MDA allows devices that are "substantially equivalent" to preexisting devices to avoid the PMA process in order to permit them to compete with grandfathered devices. See 21 U.S.C. § 360e(b)(1)(B). See generally *Medtronic,* 518 U.S. at ___, 116 S.Ct. at 2247.

Manufacturers of "substantially equivalent" Class III devices must submit to a limited form of review known as "premarket notification" to the FDA (the process is also known as a "§ 510(k) process"), which allows the device to be marketed without further regulatory analysis if the FDA decides that it is "substantially equivalent" to a preexisting device. *Medtronic,* 518 U.S. at ___, 116 S.Ct. at 2247. The § 510(k) notification process is limited in scope when contrasted to the PMA process. Whereas the PMA process requires about 1,200 hours of review, the § 510(k) process is completed in an average of only 20 hours. *Medtronic,* 518 U.S. at ___, 116 S.Ct. at 2247. Section 510(k) notification requires little information and is seldom rejected by the FDA. *Medtronic,* 518 U.S. at ___, 116 S.Ct. at 2247.[3] The PMA procedure was followed in the instant cases.

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[3] Another exception to the PMA process permits a Class III device that receives an "Investigational Device Exemption" (IDE) from the FDA to be tested on human subjects without obtaining PMA approval. 21 U.S.C. §§ 360e(a), 360j(g). In this case, the CVS catheter obtained an IDE from the FDA in September 1984, prior to defendant's submission of the PMA application.

II

The Constitution provides that the laws of the United States "shall be the supreme Law of the Land * * * any Thing in the Constitution or Laws of any state to the Contrary notwithstanding." U.S. Const., art. VI. State law that conflicts with Federal law is "without effect." *Maryland v. Louisiana,* 451 U.S. 725, 746, 101 S.Ct. 2114, 2129, 68 L.Ed.2d 576, 595 (1981). Nevertheless, when considering a preemption question, there is an assumption that a federal law will not supersede the historic police powers of states unless the purpose of Congress is clear and manifest. *Cipollone v. Liggett Group, Inc.,* 505 U.S. 504, 516, 112 S.Ct. 2608, 2617, 120 L.Ed.2d 407, 422 (1992) (*Cipollone*); *Medtronic,* 518 U.S. at ___, 116 S.Ct. at 2250.

Congressional purpose is the "ultimate touchstone" in every preemption case. *Medtronic,* 518 U.S. at ___, 116 S.Ct. at 2250, quoting *Retail Clerks International Association v. Schermerhorn,* 375 U.S. 96, 103, 84 S.Ct. 219, 222, 11 L.Ed.2d 179, 184 (1963). Congress' intent may be stated explicitly in the language of the statute or implicitly contained in its structure and purpose. *Cipollone,* 505 U.S. at 516, 112 S.Ct. at 2617, 120 L.Ed.2d at 422-23; *Medtronic,* 518 U.S. at ___ - ___, 116 S.Ct. at 2250-51. Absent an express congressional command, state law is pre-empted "if that law actually conflicts with federal law, [citation], or if federal law so thoroughly occupies a legislative field 'as to make reasonable the inference that Congress left no room for the States to supplement it. [Citation.]'" *Cipollone,* 505 U.S. at 516, 112 S.Ct. at 2617, 120 L.Ed.2d at 423.

Section 360k(a) of the MDA provides in pertinent part:

> "[N]o State or political subdivision of a State may establish or continue in effect with respect to a device intended for human use any requirement—
>
> (1) which is different from, or in addition to, any requirement applicable under this chapter to the device, and
>
> (2) which relates to the safety or effectiveness of the device or to any other matter included in a requirement applicable to the device under this chapter." 21 U.S.C. § 360k(a).

Although section 360k(a) expressly portends to preempt state law, it does so ambiguously. *Medtronic,* 518 U.S. at ___, ___, 116 S.Ct. at 2250, 2255.

In *Medtronic,* the Supreme Court noted that the scope of federal preemption under section 360k is ambiguous because the language of the statute "is not entirely clear." 518 U.S. at ___, 116 S.Ct. at 2255. This fact, coupled with the express congressional grant of authority to the FDA to implement the provisions of the MDA (see 21 U.S.C. § 360k(b)), rendered the FDA "uniquely qualified" to determine whether a particular form of state law conflicts with the MDA's objectives. *Medtronic,* 518 U.S. at ___ - ___, 116 S.Ct. at 2255-56. These considerations provided sufficient reason to give "substantial weight" to the FDA's construction of the statute. *Medtronic,* 518 U.S. at ___, 116 S.Ct. at 2256.[4]

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[4] The dissenting justices in *Medtronic* concluded that it was improper to resort to the FDA's interpretation of section 360k because they believed the statute was clear. *Medtronic,* 518 U.S. at ___, 116 S.Ct. at 2263 (O'Connor, J., concurring in part and dissenting in part).

The *Medtronic* Court found the following FDA regulations most salient in resolving the preemption question. See *Medtronic*, 518 U.S. at ___, 116 S.Ct. at 2257. "State * * * requirements are preempted only when the [FDA] has established specific counterpart regulations or * * * other specific requirements applicable to a particular device * * *." 21 C.F.R. § 808.1(d) (1995). Further, section 360k(a) "does not preempt State or local requirements of general applicability where the purpose of the requirement relates either to other products in addition to devices (*e.g.*, requirements such as general electrical codes, and the Uniform Commercial Code (warranty of fitness)), or to unfair trade practices in which the requirements are not limited to devices." 21 C.F.R. § 808.1(d)(1) (1995). See also 21 C.F.R. § 808.1(d)(6)(ii) (1995).

The majority in *Medtronic* emphasized that the primary concern of the MDA was that preemption occur only where a "particular state requirement" threatened to interfere with a "specific federal interest." 518 U.S. at ___, 116 S.Ct. at 2257. The Supreme Court then essentially identified a two-pronged inquiry in this type of case. First, the "specific" federal requirements must be reviewed; if found "applicable to the device" in question, the requirements will preempt state law only if they are "specific counterpart regulations" or "specific" to a "particular device." *Medtronic*, 518 U.S. at ___, 116 S.Ct. at 2257.

Second, the "particular" state requirements must be examined. In order to be preempted, state requirements must, "with respect to" medical devices, be "different from, or in addition to" federal requirements, and relate "to the safety or effectiveness of the device or to any other matter included in a requirement applicable to the

device." *Medtronic*, 518 U.S. at ___, 116 S.Ct. at 2257. State requirements of "general applicability" are not preempted except where they have "the effect of establishing a substantive requirement for a specific device." 21 C.F.R. § 808.1(d)(6)(ii) (1995); *Medtronic*, 518 U.S. at ___, 116 S.Ct. at 2257.

The Supreme Court cautioned that preemption analysis under the MDA "require[s] a careful comparison" between the assertedly preempting federal requirement and the allegedly preempted state requirement to determine whether they fall within the scope of the statute and regulations. *Medtronic*, 518 U.S. at ___ - ___, 116 S.Ct. at 2257-58.

The *Medtronic* Court was divided as to whether state common-law damages actions could ever be preempted by the MDA. A majority of the Court held that such actions do impose "requirements" under the MDA and are therefore preempted when the other conditions are satisfied. *Medtronic*, 518 U.S. at ___, 116 S.Ct. at 2262 (O'Connor, J., concurring in part and dissenting in part).[5] The majority based this conclusion on its reading of *Cipollone*, in which the Supreme Court noted that "'[state] regulation can be as effectively exerted through an award of damages as through some form of preventive relief. * * * [Citation.]'" 505 U.S. at 521, 112 S.Ct. at 2620, 120 L.Ed.2d at 426.

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[5] Justice Breyer agreed with the discussion of the four dissenting justices on this point. *Medtronic*, 518 U.S. at ___ - ___, 116 S.Ct. at 2259-60 (Breyer, J., concurring in part and concurring in the judgment). The plurality concluded that future incidents of MDA preemption of common-law claims would be "few" or "rare." *Medtronic*, 518 U.S. at ___, 116 S.Ct. at 2259 (Stevens, J., plurality).

In *Medtronic*, the medical device in question was a pacemaker, a Class III device. The manufacturer of the pacemaker notified the FDA that it intended to market the pacemaker as a device that was "substantially equivalent" to products already on the market; it therefore took advantage of § 510(k)'s expedited review process and escaped PMA scrutiny. *Medtronic*, 518 U.S. at ___, 116 S.Ct. at 2248. Plaintiff there was injured when her pacemaker failed. She and her husband sued the manufacturer under negligence and strict liability counts, alleging defective design and manufacture, failure to warn, and inadequate instructions. 518 U.S. at ___, 116 S.Ct. at 2248.[6] The manufacturer successfully moved for summary judgment, arguing that the tort claims were preempted by the MDA. The Federal district court dismissed plaintiffs' entire complaint, and the Court of Appeals reversed in part and affirmed in part. *Lohr v. Medtronic*, 56 F.3d 1335 (11th Cir.1995).

The Supreme Court held that none of plaintiffs' state law tort claims were preempted by the MDA. *Medtronic*, 518 U.S. at ___, 116 S.Ct. at 2259. With respect to the defective design claims, the Court concluded that under the § 510(k) process, the pacemaker never had been formally reviewed for safety or efficacy; the focus of that procedure had been on equivalence, not safety. Because that process did not impose a federal "requirement," there was no preemption. *Medtronic*, 518 U.S. at ___, 116 S.Ct. at 2254.

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[6] A third count alleging breach of warranty was dismissed for failure to state a claim under Florida state law. *Medtronic*, 518 U.S. at ___, 116 S.Ct. at 2248.

Concerning plaintiffs' manufacturing and labeling claims, the manufacturer argued that the general federal regulations governing the labeling and manufacture of all medical devices were federal "requirements," sufficient to preempt plaintiff's claims. See 21 C.F.R. §§ 801.109, 820.20-820.198 (1995). The Supreme Court rejected that contention, observing that the federal labeling and manufacturing regulations "reflect important but entirely generic concerns about device regulation generally, not the sort of concerns" contemplated by the preemption provision of the MDA. *Medtronic*, 518 U.S. at ___, 116 S.Ct. at 2258. In addition, the general state common-law requirements in the case were not specifically developed "with respect to" medical devices and were not "the kinds of requirements" that would impede the implementation and enforcement of specific federal requirements. *Medtronic*, 518 U.S. at ___, 116 S.Ct. at 2258. Accordingly, none of the claims based on defective manufacturing or labeling were preempted by the MDA.

III

In the case sub judice, defendant submitted an application to the FDA for approval of its CVS catheter pursuant to section 360e(c)(1) of the MDA. In August 1989, the Obstetrics and Gynecology Devices Panel, an FDA advisory committee, reviewed and recommended approval of the application. The FDA's Center for Devices and Radiological Health approved the application and notified defendant on August 9, 1990. See 55 Fed.Reg. 42779 (1990).

Defendant urges that the *Medtronic* decision is not controlling since the CVS catheter, unlike the pacemaker at issue in *Medtronic*, "ran the gauntlet" of PMA review and obtained FDA approval for its safety and effectiveness. We agree that the facts in the present case are different from those in *Medtronic* because the medical device here underwent rigorous PMA scrutiny. Yet, we are obliged to follow the analytical framework and guidance provided by the Supreme Court in that case.

One prong in the *Medtronic* analysis is whether there is a "specific" federal requirement "applicable to the device" at issue. Whether the PMA review process is sufficiently concrete to impose such a preempting federal requirement was not considered by the Supreme Court, but was addressed by several courts prior to that ruling. Most of those decisions hold that PMA review constitutes a specific federal "requirement" within the meaning of section 360k and regulation section 808.1(d). See, e.g., *Martello v. Ciba Vision Corp.*, 42 F.3d 1167, 1169 (8th Cir.1994); *Stamps v. Collagen Corp.*, 984 F.2d 1416, 1421-22 & n. 3 (5th Cir.1993). But see *Kennedy v. Collagen Corp.*, 67 F.3d 1453, 1458-60 (9th Cir.1995).[7] We conclude, as have the majority of courts, that the PMA process is a specific federal requirement.

The second prong to be considered is whether the corresponding state requirement was "specifically developed

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[7] In the interpretation of a federal statute, the decisions of the federal courts are controlling on Illinois courts. *Golden Bear Family Restaurants, Inc. v. Murray*, 144 Ill.App.3d 616, 619-20, 98 Ill.Dec. 459, 494 N.E.2d 581 (1986); *Arnold v. Babcock & Wilcox Co.*, 154 Ill.App.3d 863, 870, 107 Ill.Dec. 554, 507 N.E.2d 218 (1987), *aff'd*, 123 Ill.2d 67, 121 Ill.Dec. 253, 525 N.E.2d 59 (1988).

'with respect to' medical devices." *Medtronic*, 518 U.S. at ___, 116 S.Ct. at 2258. The *Medtronic* Court held that common-law claims challenging the manufacturing and labeling of medical devices were not preempted by the MDA because they were simply "general obligations" imposed by the State on manufacturers; they were not state requirements specifically developed "with respect to" medical devices. 518 U.S. at ___, 116 S.Ct. at 2258.

Here, plaintiffs' common-law claims based on the manufacture of the CVS catheter, the failure to warn, and inadequate instructions, are also "general obligations" applicable to all manufacturers and, under the holding in *Medtronic*, are not requirements specifically established for medical devices. Therefore, they are not preempted under the MDA. Plaintiffs' claims based on defective design and inadequate testing allege that defendant defectively designed and failed to adequately test the CVS catheter. Although these allegations relate to the specific medical device at issue here, they arise, nevertheless, from general duties applicable to every manufacturer. The *Medtronic* Court explained:

> "The legal duty that is the predicate for the Lohrs' negligent manufacturing claim is the *general duty of every manufacturer to use due care to avoid foreseeable dangers in its products*. Similarly, the predicate for the failure to warn claim is the *general duty to inform users and purchasers of potentially dangerous items of the risks involved in their use*. These general obligations are no more a threat to federal requirements than would be a state-law duty to comply with local fire prevention regulations and zoning codes, or to use due care in the training and supervision of a workforce. *These state requirements therefore*

> *escape pre-emption, not because the source of the duty is judge-made common-law rule, but rather because their generality leaves them outside the category of requirements that § 360k envisioned to be 'with respect to' specific devices such as pacemakers.*" (Emphasis added.) *Medtronic*, 518 U.S. at ___, 116 S.Ct. at 2258.

Similarly here, plaintiffs' claims emanate from general common-law duties and are not the sort of state requirement that section 360k was intended to preempt.

Defendant urges that, as a matter of public policy, allowing this case to go to a jury would thwart Congress' intent to encourage the development of ground-breaking medical devices that operate to improve the health and longevity of the American people. Although Congress' desire to promote the development of medical technology was clearly expressed by the passage of the MDA, its legislative history indicates that "any fears regarding regulatory burdens were related more to the risk of *additional* federal and state regulation rather than the danger of preexisting duties under common law." *Medtronic*, 518 U.S. at ___, 116 S.Ct. at 2253. Moreover, any such concern was "far outweighed" by Congress' concern for the safety of those who use medical devices. *Medtronic*, 518 U.S. at ___, 116 S.Ct. at 2253.

Accordingly, we conclude that plaintiffs' common-law tort claims, based as they are upon general liability principles, are not preempted by the MDA.

IV

Plaintiffs' remaining claims, alleging breaches of express warranty and implied warranties of merchant-

ability and fitness, were not addressed by the *Medtronic* Court as to whether these types of claims were preempted by the MDA.

Breach of warranty claims, unlike the negligence and strict liability claims raised by plaintiffs, are not common-law tort actions, but are sanctioned by positive legislative enactments of state law. See 810 ILCS 5/2-313 (West 1994); 810 ILCS 5/2-314 (West 1994). They therefore present a different question than the one the *Medtronic* Court addressed.

We turn to plaintiffs' claim that defendant breached the implied warranties of merchantability and fitness. The FDA regulations specifically provide, as an example of a permissible general requirement, that the Uniform Commercial Code warranty of fitness is not preempted. 21 C.F.R. § 808.1(d)(1) (1995); *Medtronic*, 518 U.S. at ___, 116 S.Ct. at 2257. Because these state requirements are of "general applicability," and not "specifically developed 'with respect to' medical devices," they do not fall within the purview of section 360k. We conclude that these claims are not preempted by the MDA.

Concerning the breach of express warranty claims, plaintiffs allege that defendant marketed its product with the express warranty that the CVS catheters were fit for the purpose intended, were of marketable quality and free from defects, and would not injure the fetuses of pregnant women.

Our review of this question begins with the Supreme Court's decision in *Cipollone*. There, plaintiff brought numerous claims, including one alleging breach of express warranty, against a cigarette manufacturer based on certain statements in its advertisements made to his

deceased mother. *Cipollone*, 505 U.S. at 508, 112 S.Ct. at 2613, 120 L.Ed.2d at 418. Federal law required that all cigarette packages contain a health warning, and a federal preemption provision precluded states from imposing a requirement with respect to the advertising of cigarettes whose packages provided the mandated federal warning. The *Cipollone* plurality concluded the manufacturer's express warranty that smoking did not "present any significant health consequences" was not preempted by the federal provision because the warranty was a "contractual commitment voluntarily undertaken" by the cigarette manufacturer. *Cipollone*, 505 U.S. at 525-26, 112 S.Ct. at 2622, 120 L.Ed.2d at 428-29. The plurality reasoned that "[a] manufacturer's liability for breach of an express warranty derives from, and is measured by, the terms of that warranty. Accordingly, the 'requirements' imposed by an express warranty claim are not 'imposed under State law,' but rather *imposed by the warrantor*." (Emphasis in original.) *Cipollone*, 505 U.S. at 525, 112 S.Ct. at 2622, 120 L.Ed.2d at 428.

In the context of the MDA, previously there was a split of authority in the federal courts with regard to whether a breach of express warranty claim was preempted. Compare *Martin v. Telectronics Pacing Systems, Inc.*, 70 F.3d 39, 42 (6th Cir.1995), cert. granted and judgment vacated by, 518 U.S. ___, 116 S.Ct. 2576, 135 L.Ed.2d 1091 (1996), and *Duvall v. Bristol-Myers-Squibb Co.*, 65 F.3d 392, 400-01 (4th Cir.1995), cert. granted and judgment vacated by, 518 U.S. ___, 116 S.Ct. 2575, 135 L.Ed. 2d 1090 (1996) (preemption) with *Michael v. Shiley, Inc.*, 46 F.3d 1316, 1327 (3d Cir.1995), and *Kennedy*, 67 F.3d at 1459-60 (no preemption). Courts concluding that ex-

press warranty claims were not preempted followed the lead in *Cipollone*. In *Michael v. Shiley*, the court stated:

> "Express warranties arise from the representations of the parties which are made the basis of the bargain and do not result from the independent operation of state law. * * * The parties to a contract, not the state, define the substantive obligations of the contract and hence any express warranties. While the state provides for the enforcement of the parties' bargain, it does not define each party's duties." 46 F.3d at 1325.

Because the MDA preempted only state requirements having the force of law, not private agreements, express warranties were not preempted. *Shiley*, 46 F.3d at 1325. We concur.

Decisions holding that express warranty claims are preempted by the MDA were limited to facts involving express warranties based on FDA-mandated labeling, packaging, and advertising, not claims based on a manufacturer's voluntarily-made representations regarding its product. *Duvall*, 65 F.3d at 400-01. See also *King v. Collagen Corp.*, 983 F.2d 1130, 1135 (1st Cir.1993) (opinion of Torruella, J.). In addition, the judgments in *Martin* and *Duvall* since have been vacated by the Supreme Court, as earlier noted. Accordingly, those cases no longer have the force of law.

In the present case, the assertions forming the bases of the breach of express warranty claims arise by defendant's own express representations, not by a state-imposed duty. Therefore, express warranties by a manufacturer are not state "requirements" and thus fall outside of the scope of section 360k.

From the foregoing, we conclude that none of plaintiffs' state-law claims are preempted by the MDA and the circuit courts erred in granting defendant's motions for summary judgment. Accordingly, the judgments of the circuit courts are reversed and the causes are remanded for further proceedings not inconsistent with this opinion.

Reversed and remanded.

DiVITO and BURKE, JJ., concur.

(Letterhead of)

ILLINOIS SUPREME COURT
JULEANN HORNYAK, CLERK
SUPREME COURT BUILDING
SPRINGFIELD, ILLINOIS 62701
(217) 782-2035

December 4, 1996

Mr. Jeffrey Singer
Segal, McCambridge, Singer & Mahoney. Ltd.
20 South Clark Street
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Chicago, IL 60603

No. 82017 - Sarah Kernats, a Minor, etc., et al., respondents, v. Smith Industries Medical Systems, Inc., etc., petitioner. Leave to appeal, Appellate Court, First District.

The Supreme Court today DENIED the petition for leave to appeal in the above entitled cause.

The mandate of this Court will issue to the Appellate Court on December 26, 1996.

SUPREME COURT OF ILLINOIS
WEDNESDAY, DECEMBER 4, 1996

THE FOLLOWING CASES ON THE LEAVE TO APPEAL DOCKET WERE DISPOSED OF AS INDICATED:

No. 80359 People State of Illinois, respondent, v. Anthony Smith, petitioner. Leave to appeal, Appellate Court, First District. (1-93-3519, 1-93-3520)

Petition for leave to appeal denied.

No. 80632 People State of Illinois, respondent, v. Loren Ethridge, petitioner. Leave to appeal, Appellate Court, Fifth District. (5-94-0107)

Petition for leave to appeal denied.

No. 80768 People of the State of Illinois ex rel. Silvette Lemardo, etc., respondent, v. Yusuf Broachwala, petitioner. Leave to appeal, Appellate Court, First District. (1-92-0189)

Petition for leave to appeal denied.

No. 80908 People State of Illinois, respondent, v. Theresita Aprieto, petitioner. Leave to appeal, Appellate Court, First District. (1-94-3676)

Petitioner having failed to file a petition for leave to appeal within the time allowed by order, this cause is DISMISSED.

No. 80995 People State of Illinois, petitioner, v. Tyreese Tooles, respondent. Leave to appeal, Appellate Court, Third District. (3-94-0627)

PETITION FOR LEAVE TO APPEAL ALLOWED.

This case is consolidated with Case Nos. 80997 & 81002.

No. 80997 People State of Illinois, petitioner, v. William Farmer, respondent. Leave to appeal, Appellate Court, Third District. (3-94-0163, 3-94-0164, 3-94-0165)

PETITION FOR LEAVE TO APPEAL ALLOWED.

This case is consolidated with Case Nos. 80995 & 81002.

No. 82011 City of Chicago, respondent, v. American Federation of State, County and Municipal Employees, etc., petitioner. Leave to appeal, Appellate Court, First District. (1-95-2055)

Petition for leave to appeal denied.

No. 82012 People State of Illinois, respondent, v. Thomas Ross, petitioner. Leave to appeal, Appellate Court, First District. (1-94-1789)

Petition for leave to appeal denied.

No. 82014 People State of Illinois, respondent, v. George Marshall, etc., petitioner. Leave to appeal, Appellate Court, First District. (1-94-0914)

Petition for leave to appeal denied.

No. 82015 People State of Illinois, respondent, v. Jose Medrano, petitioner. Leave to appeal, Appellate Court, First District. (1-94-2069)

Petition for leave to appeal denied.

No. 82016 People State of Illinois, respondent, v. Danny McGhee, petitioner. Leave to appeal, Appellate Court, First District. (1-95-1717)

Petition for leave to appeal denied.

No. 82017 Sarah Kernats, a Minor, etc., et al., respondents, v. Smith Industries Medical Systems, Inc., etc., petitioner. Leave to appeal, Appellate Court, First District. (1-94-4386, 1-95-3128, 1-95-3129)

Petition for leave to appeal denied.

No. 82018 People State of Illinois, respondent, v. Donta Childs, petitioner. Leave to appeal Appellate Court, First District. (1-94-4405)

Petition for leave to appeal denied.

No. 82019 People State of Illinois, respondent, v. Clarence Lewis, Jr., petitioner. Leave to appeal, Appellate Court, First District. (1-94-1752)

Petition for leave to appeal denied.

No. 82020 People State of Illinois, respondent, v. Gamel Scharoubim, petitioner. Leave to appeal, Appellate Court, First District. (1-95-3126)

Petition for leave to appeal denied.

[November 17, 1994]

IN THE CIRCUIT COURT OF COOK COUNTY
COUNTY DEPARTMENT, LAW DIVISION

SARAH KERNATS, a minor, by CYNTHIA KERNATS, her mother and next friend, CYNTHIA KERNATS, individually, and ANDREW KERNATS,	)	
Plaintiffs,	)	
v.	)	No. 92 L 13573
HOWARD GRUNDY, M.D., et al.,	)	
Defendants.	)	

ORDER

This Cause comes upon defendant SMITHS INDUSTRIES MEDICAL SYSTEMS' motion for summary judgment, due notice given and the Court fully advised in the premises:

IT IS HEREBY ORDERED said motion for summary judgment is granted. This is a final and appealable order and there is no just cause to delay its enforcement or appeal.

ENTER:

/s/ Joseph N. Casciato
Judge

Dated: November 17, 1994

[Dated June 22, 1995]

**IN THE CIRCUIT COURT OF
COOK COUNTY, ILLINOIS
COUNTY DEPARTMENT, LAW DIVISION**

JOYCE OSHODI, Individually and as mother and next friend of KENNETH OSHODI, a minor,	)	
Plaintiffs,	)	
v.	)	94 L 7177
MICHAEL REESE HOSPITAL AND MEDICAL CENTER, et al.,	)	
Defendants.	)	

MEMORANDUM ORDER

1. Background

Plaintiff Joyce Oshodi alleges that she was injured and her son Kenneth suffered limb deformities as a result of chorionic villus sampling (CVS) genetic testing performed in 1986. Defendant Smiths Industries Medical Systems, Inc. (SIMS) designed and distributed the CVS catheter used in the testing. Defendant SIMS moves for summary judgment asserting that Plaintiff's claims against Defendant SIMS (as set forth in Counts XXII through XXIV of Plaintiff's First Amended Complaint) are preempted by the Medical Devices Amendments of 1976, 21 U.S.C. §§360c-3601 (MDA).

2. Issue

The resolution of this motion turns on the meaning of 21 U.S.C. §360k(a) which provides:

> [E]xcept as provided in subsection (b) of this section, no State or political subdivision of a State may establish or continue in effect with respect to a device intended for human use any requirement— (1) which is different from, or in addition to, any requirement applicable under this chapter to the device, and (2) which relates to the safety or effectiveness of the device or to any other matter included in a requirement applicable to the device under this chapter.

The issue is whether this federal statute preempts Plaintiff's common law claims as set out in Counts XXII through XXIV of the First Amended Complaint.

3. Discussion

Plaintiff contends that this statutory language preempts inconsistent regulations and statutes but not common law claims. Under 21 U.S.C. §360k(a), States or political subdivisions of a state are prohibited from establishing any "requirement" which differs from or adds to any "requirement" imposed under the MDA for certain types of medical devices. The United States Supreme Court stated in *Cipollone Liggett Group, Inc.*, 112 S.Ct. 2608, 2620; 120 L.Ed.2d 407 (1992), that "[T]he phrase 'no requirement or prohibition' sweeps broadly and suggests no distinction between positive enactments and common law; to the contrary, those words easily encompass obligations that take the form of common law rules."

The Illinois Appellate Court, Second District, has recently addressed the term "requirement" in the context of §360k(a). Citing *Cipollone* and 21 C.F.R. §808.1(b), the Court held that the term "requirement" includes court decisions. *Kus v. Sherman Hospital*, 268 Ill.App.3d 771 (2nd Dist. 1995). The Court is aware that *Kus* conflicts with *Haudrich v. Howmedica, Inc.*, 267 Ill.App.3d 630 (5th Dist. 1994). The Court finds unpersuasive the reasoning in *Haudrich* which would avoid preemption by a strained and narrow interpretation of "requirement." The Court agrees with the *Kus* opinion that:

> Thus, States may not impose requirements differing from or adding to the FDA requirements which relate to the safety or effectiveness of the device in question. A State requirement may stem from any requirement established by a State, including statutes, regulations, ordinances, or court decisions. 21 C.F.R. §808.1(b) (1993); see also *San Diego Building Trades Council, Millmen's Union, Local 2020 v. Garmon* (1959), 359 U.S. 236, 247, 3 L.Ed.2d 775, 784, 79 S.Ct. 773, 780 ("regulation can be as effectively exerted through an award of damages as through some form of preventive relief. The obligation to pay compensation can be, indeed is designed to be, a potent method of governing conduct and controlling policy"). 268 Ill.App.3d at 777.

Plaintiff also argues that her claims are not preempted because the CVS catheter at issue had not received FDA approval at the time Plaintiff underwent the CVS procedure. Plaintiff is correct to the extent that the CVS catheter at issue had not yet received "pre-market approval." However, the device had already been granted an Investigational Device exemption (IDE). (See Exhibit

B to Motion for Summary Judgment, IDE Approval Letter dated September 19, 1984). As stated in *Slater v. Optical Radiation Corp.*, 961 F.2d 1330 1333 (7th Cir. 1992), "the FDA will not grant an investigational-device exemption unless it believes that the device has sufficient promise of being proved safe and effective to justify the risk of its being used on human beings." The Seventh Circuit stressed the important policy reason for preemption that "if experimental procedures are subject to hindsight evaluation by juries, so that failed experiments threaten to impose enormous tort liability on the experimenter, there will be fewer experimental treatments, and patients will suffer." *Id.* at 1334. Therefore, when a device has been granted an IDE, claims relating to safety and effectiveness of the device are preempted. *Gile v. Optical Radiation Corp.*, 22 F.3d 540 (3rd Cir. 1994); *Slater v. Optical Radiation Corp.*, 961 F.2d 1330 (7th Cir. 1992); *Covey v. Surgidev Corp.*, 815 F. Supp. 1089 (N.D.Ohio 1993); *Hunsaker v. Surgidev Corp.*, 818 F.Supp. 744 (M.D. Pa. 1992). Congress plainly did not want state interference to discourage development of such promising devices.

Plaintiff cites 21 U.S.C. §360k(a) and 21 C.F.R. §808.1(d) for the proposition that in order for the MDA to have preemptive effect, there must be regulations specifically pertaining to the device at issue. Since there are no such device-specific regulations for CVS catheters, Plaintiff reasons that there is no preemption of Plaintiff's claims. However, the rigorous procedural requirements of the IDE approval process constitute "specific requirements" within the meaning of §360k(a) and §808.1(d). See *Gile v. Optical Radiation Corp.*, 22 F.3d 540 (3rd Cir. 1994); *Slater v. Optical Radiation Corp.*, 961 F. 2d 1330

(7th Cir. 1992); *Covey v. Surgidev Corp.*, 815 F.Supp. 1089 (N.D.Ohio 1993); *Hunsaker v. Surgidev Corp.*, 818 F.Supp. 744 (M.D. Pa. 1992). There is nothing in the words of the statute that any "requirement" be substantive as to safety and effectiveness rather than procedural in nature. The Seventh Circuit rejected Plaintiff's argument as follows:

> The argument assumes that the only federal requirement that might relate to the safety or effectiveness of the design of a medical device would be an actual specification of that design. The preemption provision does not say this, and so cramped an interpretation would cripple the exemption for investigational devices. The FDA can hardly be expected to specify the safe and effective design of a device when it is still experimental. If there were a known safe and effective design, the device would no longer be experimental. The point of the experiment is to find out whether it is safe and effective. *Public Citizen Health Research Group v. FDA,* supra, 704 F.2d at 1283. In the experimental phase the appropriate regulations of safety and effectiveness are procedural rather than substantive ones. They do not specify the safe and effective design; they specify the procedures for determining whether the experimental design is safe and effective. These are requirements relating to safety and effectiveness and they can therefore have preemptive effect. 961 F.2d at 1333.

Plaintiff requests additional time to gather discovery, including FDA files, to support her theory that SIMS gained FDA approval by misrepresentation. This request has no merit. This Court is not the proper forum in which to launch such an inquiry or review. The prospect

of such an inappropriate inquiry merely adds weight to SIMS' argument that Congress intended preemption in cases such as this.

Applying the foregoing reasoning and authority to the various Counts, the Court finds summary judgment is appropriate as to each. Count XXII alleges defective design and manufacture, inadequate warnings, and inadequate instructions. Under *Slater*, such claims, are preempted. Count XXIII alleges breach of express and implied warranties. As stated in *King v. Collagen Corp.*, 983 F.2d 1130 (1st Cir. 1993), express warranty claims could only arise out of the FDA-approved labeling and packaging. Since such claims effectively would impose additional or different requirements on the device's labeling and packaging, they are preempted. Similarly, implied warranty claims would also impose requirements beyond those imposed under the MDA. Therefore, the implied warranty claims are also preempted. Count XXIV alleges negligence, failure to warn and inadequate or negligent testing. Under *Slater*, such claims are preempted.

In summary, since all of Plaintiff's claims are preempted by the MDA, Defendant SIMS' motion for summary judgment is granted. The Court further finds that there is no just reason for delaying enforcement or appeal of this order.

This case is set for status as to the remaining parties on July 6, 1995 at 10:15 a.m.

June 22, 1995

/s/ Robert V. Boharic
Judge

[June 30, 1995]

IN THE CIRCUIT COURT OF COOK COUNTY
COUNTY DEPARTMENT, LAW DIVISION

MARY SUSAN WILLIAMS, as mother and next friend of JOHN CALVIN WILLIAMS, a minor,	)	
Plaintiff,	)	
v.	)	No. 93 L 015781
ALAN CADKIN, M.D., et al.,	)	
Defendants.	)	

ORDER

This cause comes upon motion of defendant SMITHS INDUSTRIES MEDICAL SYSTEMS, INC., due notice given, parties present thru counsel and the Court fully advised in the premises:

IT IS HEREBY ORDERED defendant SMITHS INDUSTRIES' motion for summary judgment is granted. There exists no just cause to delay enforcement of this final and appealable order nor its appeal.

ENTER:

/s/ Jennifer Duncan Brice
Judge

Dated: June 30, 1995

No. 96-1405

Supreme Court, U.S.
FILED
APR 4 1997
OFFICE OF THE CLERK

IN THE

Supreme Court of the United States

OCTOBER TERM 1996

SMITHS INDUSTRIES MEDICAL SYSTEMS, INC.,
Petitioner,

v.

SARAH KERNATS, a minor, by CYNTHIA KERNATS, her mother and next friend, CYNTHIA KERNATS, individually, and ANDREW KERNATS,
Respondents.

SMITHS INDUSTRIES MEDICAL SYSTEMS, INC.,
Petitioner,

v.

JOYCE OSHODI, individually and as mother and next friend of KENNETH OSHODI, a minor,
Respondents.

SMITHS INDUSTRIES MEDICAL SYSTEMS, INC.,
Petitioner,

v.

MARY SUSAN WILLIAMS, as mother and next friend of JOHN CALVIN WILLIAMS, a minor,
Respondents.

On Petition for Writ of Certiorari to the Appellate Court of Illinois, First District

RESPONDENTS' BRIEF IN OPPOSITION

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QUESTION PRESENTED

Whether the Medical Device Amendments of 1976 preempt state law claims based on general obligations imposed on manufacturers when Class III medical devices which have obtained pre-market approval or investigational device exemptions are involved.

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APPLICABLE STATUTES AND RULES

This case involves §360k(a) of the Medical Device Amendments of 1976, which provides as follows:

> (a) Except as provided in subsection (b) of this Section, no State or political subdivision of a State may establish or continue in effect with respect to a device intended for human use any requirement—
>
> (1) which is different from, or in addition to, any requirement applicable under this chapter to the device, and
>
> (2) which relates to the safety or effectiveness of the device or to any other matter included in a requirement applicable to the device under this chapter.

21 U.S.C. §360k(a) (Supp. 1992).

RESPONDENTS' BRIEF IN OPPOSITION

Respondents request that this Court deny the petition for writ of certiorari seeking review of an opinion of the Appellate Court of Illinois for the First Judicial District.

STATEMENT OF THE CASE

This case consists of three separate cases, *Kernats v. SIMS*, *Oshodi v. SIMS* and *Williams v. SIMS*, which were consolidated on appeal due to a similarity of issues. In each of these cases, the minor plaintiff's mother underwent chorionic villus sampling ("CVS") during pregnancy. CVS is a medical procedure in which fetal tissue samples are obtained during the first trimester and tested for genetic abnormalities. The minor plaintiffs were subsequently born with limb deformities.

Respondents filed these cases in the Circuit Court of Cook County, Illinois, against Smiths Industries Medical Systems, Inc. ("SIMS"), which manufactured, distributed and sold the CVS catheter used in the procedure. Respondents' claims were based upon theories of strict products liability, common law negligence, and breach of express and implied warranties.

SIMS filed motions for summary judgment on the grounds that they were pre-empted by the Medical Device Amendments of 1976 ("MDA"). 21 U.S.C. §360c-360l. The Circuit Court of Cook County granted the motions for summary judgment finding that respondents' claims had been pre-empted.

Respondents appealed to the Illinois Appellate Court, First Judicial District. Relying on *Medtronic, Inc. v. Lohr*, 116 S.Ct. 2240 (1996), the Illinois Appellate Court found that respondents' state law claims were not pre-empted by the MDA. The opinion of the Appellate Court

of Illinois is reported at 283 Ill.App.3d 455, 669 N.E.2d 1300 (1st Dist. 1996).

In *Medtronic,* the recipient of a pacemaker, which was a Class III medical device and had been approved for marketing under the MDA as a device substantially similar to devices already on the market, brought an action against the manufacturer of the pacemaker asserting claims of negligence and strict liability. This Court held that none of the plaintiffs' common law claims were pre-empted by the MDA.

In determining the extent to which the MDA pre-empts state law claims, this Court noted that while §360k(a) is an express pre-emption provision, the scope of federal pre-emption under §360k is ambiguous. This ambiguity, together with Congress' express grant of authority to the Food and Drug Administration ("FDA") to implement the MDA, provided a "sound basis" for giving substantial weight to the agency's view of the statute. 116 S.Ct. at 2256.

The FDA regulations provide that state requirements are pre-empted "'only' when the FDA has established 'specific counterpart regulations or . . . other specific requirements applicable to a particular device.' 21 C.F.R. §808.1(d) (1995)." *Id.* at 2257. They further provided that the statute "is not intended to pre-empt 'State or local requirements of general applicability where the purpose of the requirement relates either to other products in addition to devices . . . or to unfair practices in which the requirements are not limited to devices.' §808.1(d)(1)." *Id.*

Based on the language of the statute and the FDA regulations, this Court concluded that in order for pre-emption to occur, certain criteria must be met. First, federal requirements "must be 'applicable to the device'

in question"; they pre-empt state law "only if they are 'specific counterpart regulations' or 'specific' to a 'particular device.'" *Id.* at 2257.

Second, the state requirements "must be 'with respect to' medical devices and 'different from, or in addition to' federal requirements." *Id.* at 2257. State requirements "must also relate 'to the safety or effectiveness of the device or to any other matter included in a requirement applicable to the device'". *Id.* State requirements of "general applicability" "are not pre-empted except where they have 'the effect of establishing a substantive requirement for a specific device.'" *Id.* Thus, in order to determine whether there is pre-emption, a "careful comparison between the allegedly pre-empting federal requirement and the allegedly pre-empted state requirement" is necessary. *Id.* at 2257-58.

Applying this analysis, the Illinois Appellate Court held that, despite the fact that the medical device in question had been granted pre-market approval ("PMA"), the respondents' negligence, strict liability, and breach of implied warranty claims were not pre-empted because those claims were based upon "general obligations" applicable to all product manufacturers. The Court further held that respondents' breach of express warranty claims were not pre-empted because the assertions forming the bases of the breach of express warranty claims arose from SIMS' own express representations, not by a state-imposed duty. Since express warranties by a manufacturer were not state "requirements", they fell outside of the scope of §360k.

THE MEDICAL DEVICE AMENDMENTS OF 1976

The present case involves the scope of the preemption provision contained in the MDA. The MDA classifies medical devices as Class I, II or III devices. 21 U.S.C. 360c(a). The degree of danger posed to the public by the medical device determines its classification. Class III medical devices, such as the CVS catheter in question, present "a potential unreasonable risk of illness or injury" and are the most heavily regulated. 21 U.S.C. §360c(a)(1)(C)(II).

In order to market a Class III medical device, a manufacturer must provide the FDA with a "reasonable assurance" that the device is both safe and effective. 21 U.S.C. §360e(d)(2). This is accomplished by obtaining pre-market approval. To obtain pre-market approval for a Class III device, a manufacturer must submit an application which includes a bibliography of all reports concerning the device's safety and effectiveness, an outline of the device's components and properties, a description of the manufacturing process, safety data, samples of the device, copies of all proposed labeling, and any other information of the FDA requests. 21 U.S.C. §360e(c)(1). See also 21 C.F.R. §814.20. The application is referred to an advisory panel which studies the applications and submits a report and recommendation respecting approval. 21 U.S.C. §360e(c)(2). The FDA may withdraw its approval if it determines that a device previously approved is unsafe or ineffective. 21 U.S.C. §360e(c).

Not all Class III devices have received PMA approval because of two exceptions to the PMA requirement. The statute includes a grandfather provision which allows pre-1976 medical devices to remain on the market until such time as the FDA initiates and completes the

requisite PMA. See 21 U.S.C. §360e(b)(1)(A); 21 C.F.R. §814.1(c)(1). The MDA allows devices that are "substantially equivalent" to preexisting devices to avoid the PMA process so as to prevent grandfathered devices from monopolizing the market. See 21 U.S.C. §360e(b)(1)(B). *Medtronic*, 116 S.Ct. at 2247.

Manufacturers of "substantially equivalent" Class III devices must submit to a limited form of review known as "pre-market notification" or the 510(k) process, which allows the device to be marketed without further regulatory analysis if the FDA decides that it is "substantially equivalent" to a preexisting device. *Id.*

A second exception, called the "Investigational Device Exception", exempts investigational devices from the PMA process in order to encourage the development of devices. 21 U.S.C. §360j(g). Although investigational devices are not subject to the rigorous PMA process, they are subject to other regulations which set forth procedures for determining whether they are safe and effective. To obtain approval under the IDE, a manufacturer must submit an application which includes prior investigations, a description of the manufacturing process and control data, among other information. 21 U.S.C. §§360e, 360j(g). Based on the information submitted, the FDA will approve the device under the IDE unless the risks are not outweighed by the benefits, the investigation is scientifically unsound or there is reason to believe the device is ineffective. 21 C.F.R. §812.30.

ARGUMENT

I.

THE PREEMPTION ANALYSIS ESTABLISHED IN *MEDTRONIC* SUPPORTS A FINDING AGAINST PREEMPTION.

In *Medtronic* this Court considered the preemption issue with respect to a device which had been marketed pursuant to the 510(k) process. Although IDE and PMA Class III medical devices are subjected to different processes than are "substantially equivalent" devices, the preemption analysis established by this Court in *Medtronic* supports a finding against preemption.

A. The IDE and PMA processes do not constitute "specific requirements" under the MDA.

The MDA contains an express preemption clause, 21 U.S.C. § 360k(a), which provides:

> (a) Except as provided in subsection (b) of this Section, no State or political subdivision of a State may establish or continue in effect with respect to a device intended for human use any requirement—
>
> (1) which is different from, or in addition to, any requirement applicable under this chapter to the device, and
>
> (2) which relates to the safety or effectiveness of the device or to any other matter included in a requirement applicable to the device under this chapter.

21 U.S.C. §360k(a) (Supp. 1992).

Section 360k(a) expressly provides that a federal requirement must be "applicable to the device" in question before it has any preemptive effect. 21 U.S.C. §360k(a). According to FDA regulations, federal requirements preempt state law "only" if they are "specific counterpart

regulations" or "specific" to a "particular device." 21 C.F.R. §808.1(d).

The IDE and PMA processes, however, consist of general requirements applicable to all Class III medical devices; they are not device-specific. As noted by several courts, the fact that the pre-market approval process involves specific requirements "must not be confused with the pre-market approval requirement itself acting as a specific requirement." (*Walker v. Johnson & Johnson*, 217 Mich. App. 705, 714 (1996), quoting *Kennedy v. Collagen Corp.*, 67 F.3d 1453 (CA 9, 1995).) Thus, these processes are not "specific requirements" applicable to a "particular device" sufficient to trigger preemption.

B. The general duties imposed by the state law actions do not constitute "specific requirements" for a "particular device".

Even if the IDE and PMA processes did constitute "specific" federal requirements, preemption is nonetheless not warranted.

In *Medtronic,* this Court rejected the argument that any common law cause of action is a "requirement" which imposed duties "different from, or in addition to" the standards the FDA had promulgated in response to mandates under the FDA. *Medtronic,* 116 S.Ct. at 2251. Rather, this Court noted that the term "requirement" as used in §360k appears to presume that the State is imposing a specific duty upon the manufacturer. *Id.* Specifically, the language of the statute suggest that its focus is "device-specific enactments of positive law by legislative or administrative bodies, not the application of general rules of common law by judges and juries." *Id.* at 2252.

Even were state tort law to constitute a "requirement" under the statute, because the state law requirements were not specifically developed "with respect to" medical devices, pre-emption is not warranted. See *Medtronic*, 116 S.Ct. at 2258.

State requirements must be "with respect to" medical devices and "different from, or in addition to" federal requirements. *Id.* at 2257. State requirements must also relate to the "safety or effectiveness of the device or to any other matter included in a requirement applicable to the device." *Id.* at 2257. State requirements of "general applicability" "are not pre-empted except where they have 'the effect of establishing a substantive requirement for a specific device.'" *Id.*

Respondents' common-law claims based on the manufacture of the CVS catheter, the failure to warn, and inadequate instructions are "general obligations" applicable to all manufacturers. Respondents' claims based on defective design and inadequate testing allege that SIMS defectively designed and failed to adequately test the CVS catheter. While these allegations may relate to the specific medical device in question, they similarly arise from "general duties applicable to every manufacturer" as does the implied warranty of merchantability claim. The express warranty claims do not arise from a state-imposed duty.

As explained by this Court in *Medtronic*:

> "These general obligations are no more a threat to federal requirements than would be a state-law duty to comply with local fire prevention regulations and zoning codes, or to use due care in the training and supervision of a workforce. These state requirements therefore escape pre-emption, not because the source of the duty is judge-made common-law rule, but

> rather because their generality leaves them outside the category of requirements that §360k envisioned to be 'with respect to' specific devices . . ." *Medtronic*, 116 S.Ct. at 2258.

Since the state law claims are not requirements specifically established for medical devices, they are not pre-empted under the MDA. See *Connelly v. Iolab Corp.*, 927 S.W.2d 848, (Mo. 1996); *Armstrong v. Optical Radiation Corp.*, 57 Cal.Rptr. 2d 763 (Cal.Ct.App. October 29, 1996).

C. 360k does not pre-empt State requirements that are equal to, or substantially identical to, requirements imposed by or under the Act.

Even if specific federal "requirements" exist with respect to the CVS catheter, and even if state common law can be considered a "requirement" under §360k, the state requirement is not pre-empted unless it is "different from, or in addition to," the federal requirement. §360k(a)(1).

The regulations promulgated by the FDA expressly support the conclusion that §360k does not pre-empt state or local requirements "that are equal to, or substantially identical to, requirements imposed by or under the act." 21 C.F.R §808.1(d)(2) (1995). In *Medtronic*, this Court found that "[n]othing in §360k denies [the States] the right to provide a traditional damages remedy for violations of common-law duties when those duties parallel federal requirements." *Medtronic*, 116 S.Ct. at 2255. Thus, to the extent respondents' claims are for violations of common law duties which parallel federal requirements, they are not pre-empted.

II.

CONGRESSIONAL GOALS UNDERLYING THE ENACTMENT OF THE MDA WOULD NOT BE COMPROMISED IF THERE WERE NO PRE-EMPTION.

Petitioner asserts that, absent pre-emption, manufacturers will be compelled to cease the development of potentially life-saving medical devices, and that such a result would undermine Congress' goal of promoting the advancement of medical technology.

The MDA was enacted "to provide for the safety and effectiveness of medical devices for human use." *Medtronic*, 116 S.Ct. at 2253. While Congress' desire to promote the development of medical technology was also a concern, the legislative history indicates that "any fears regarding regulatory burdens were related more to the risk of *additional* federal and state regulation rather than the danger of preexisting duties under common law." *Id.* (Emphasis in original.) Furthermore, any concern of protecting the industry was "far outweighed" by concern for the safety of those who use medical devices. *Id.*

Accordingly, public policy considerations do not warrant a finding of pre-emption.

CONCLUSION

The writ of certiorari should be denied.

Respectfully submitted,

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IN THE

Supreme Court of the United States

OCTOBER TERM, 1996

SMITHS INDUSTRIES MEDICAL SYSTEMS, INC.,
Petitioner,

v.

SARAH KERNATS, a minor, by CYNTHIA KERNATS, her mother and next friend, CYNTHIA KERNATS, individually, and ANDREW KERNATS,
Respondents.

SMITHS INDUSTRIES MEDICAL SYSTEMS, INC.,
Petitioner,

v.

JOYCE OSHODI, individually and as mother and next friend of KENNETH OSHODI, a minor,
Respondents.

SMITHS INDUSTRIES MEDICAL SYSTEMS, INC.,
Petitioner,

v.

MARY SUSAN WILLIAMS, as mother and next friend of JOHN CALVIN WILLIAMS, a minor,
Respondents.

On Petition for Writ of Certiorari to the Appellate Court of Illinois, First District

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REPLY BRIEF IN SUPPORT OF PETITION FOR WRIT OF CERTIORARI

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REPLY BRIEF IN SUPPORT OF PETITION FOR WRIT OF CERTIORARI

Petitioner, Smiths Industries Medical Systems, Inc. ("SIMS"), respectfully submits this Reply Brief in Support of its Petition for Writ of Certiorari to the Appellate Court of Illinois, First District.

REASONS FOR GRANTING THE WRIT

I.

THE RECENT DECISIONS OF TWO FEDERAL APPELLATE COURTS HAVE INTENSIFIED THE CONFLICT AMONG THE LOWER COURTS REGARDING THE SCOPE OF MDA PREEMPTION.

SIMS established in its Petition for Writ of Certiorari that the lower courts have been unable to consistently apply this Court's decision in *Medtronic, Inc. v. Lohr*, 116 S.Ct. 2240 (1996). Within the past two months alone, the decisions of two Federal Appellate courts have widened the division of authority.

In *Chambers v. Osteonics Corp.*, ___ F.3d ___, 1997 WL 155113 (7th Cir. April 3, 1997), the United States Court of Appeals for the Seventh Circuit held in favor of preemption in a case involving an IDE Class III medical device. The plaintiff in *Chambers* brought a products liability action against the manufacturer of a Class III hip prosthesis that had been granted an IDE by the FDA. 1997 WL 155113 at *1.

The Seventh Circuit in *Chambers* held that the plaintiff's claims based on strict products liability and breach of implied warranty "could impose liability on [the manufacturer] for an experimental device that meets all FDA

standards and requirements but is still somehow adjudged unreasonably dangerous." *Id.* at *5. The Seventh Circuit further held that upholding the plaintiff's claims would "defeat the purpose of the investigational device exemption" and "set up a direct collision with Federal policy". *Id.* Accordingly, the Seventh Circuit held that the plaintiff's strict products liability and breach of implied warranty claims were preempted by the MDA.[1] *Id.*

The Seventh Circuit's decision in *Chambers* directly conflicts with the *Kernats* decision below, where the Illinois Appellate Court held that preemption does not apply to the Plaintiffs' strict liability and breach of implied warranty claims. The Seventh Circuit's decision in *Chambers* also conflicts with the decision of the Supreme Court of Missouri in *Connelly v. Iolab Corp.*, 927 S.W.2d 848, 853-54 (Mo. 1996). In *Connelly*, a case involving an IDE Class III device, the court held that the plaintiff's strict liability claim was not preempted.

The recent decision of the United States Court of Appeals for the Ninth Circuit in *Papike v. Tambrands, Inc.*, 107 F.3d 737 (9th Cir. February 20, 1997), has also contributed to the split of authority regarding MDA preemption. In *Papike*, the plaintiff brought suit against the manufacturer of a tampon (a Class II device) for failure to warn of the risk of toxic shock syndrome. The plaintiff argued that her failure to warn claim was not preempted by the MDA because her claim arose from "generally applicable" principles of state tort law that were not spe-

---

[1] The court held that the plaintiff's claim for negligent manufacturing was not preempted to the extent it was based on requirements that mirrored the requirements imposed by the MDA and the FDA.

cifically developed "with respect to" medical devices. *Id.* at 741.

The Ninth Circuit rejected the plaintiff's argument as inconsistent with this Court's decision in *Medtronic*. *Id.* at 741-42. The Ninth Circuit held that state law products liability claims are *not* immune from preemption merely because they arise from requirements applicable to all product manufacturers. *Id.* Rather, the Ninth Circuit held that generally applicable state law requirements *are* subject to preemption when they impose requirements that exceed or differ from specific Federal requirements. *Id.* Based on the existence of specific Federal requirements regarding tampon labeling, the Ninth Circuit concluded that the plaintiff's failure to warn claim was preempted by the MDA. *Id.*

Although *Papike* involved a Class II medical device, the Ninth Circuit's decision in that case directly conflicts with the Illinois Appellate Court's decision in *Kernats*. The basic holding underlying the *Papike* decision is that MDA preemption *does* apply to "generally applicable" state law tort claims. However, the Appellate Court in *Kernats* held that the Plaintiffs' state law tort claims are not preempted because they arise from "general duties applicable to every manufacturer". (App. at 14-16).

The Ninth Circuit's decision in *Papike* also conflicts with *Armstrong v. Optical Radiation Corp.*, 57 Cal. Rptr. 2d 763 (Cal. Ct. App. 1996), and *Walker v. Johnson & Johnson Vision Products, Inc.*, 217 Mich. App. 705 (1996). In both *Armstrong* and *Walker*—cases involving PMA Class III devices—the courts held that the plaintiffs' claims were not preempted because they arose from generally applicable state tort law.

II.

THE DIVISION OF AUTHORITY REGARDING MDA PREEMPTION WILL CONTINUE TO GROW UNLESS THIS COURT RENDERS A CONCLUSIVE DECISION.

This Court's grant of certiorari in *Medtronic, Inc. v. Lohr* provides ample proof that MDA preemption involves significant legal *and* social issues. However, the decisions cited by SIMS in its Petition and in this Reply Brief clearly demonstrate that the lower courts desperately require additional guidance from this Court.

Critical questions regarding the scope of MDA preemption remain unanswered. Does MDA preemption apply to claims that challenge the safety and effectiveness of IDE Class III devices? Of PMA Class III devices? Are product liability claims immune from preemption because they arise from "generally applicable" duties applicable to all product manufacturers? The foregoing questions are not rhetorical. The lower courts will continue to struggle with those questions unless this Court intervenes and renders a conclusive decision.

The instant Petition is *ideally* suited for acceptance by this Court. It is undisputed that the CVS catheter in controversy was first granted an IDE, and was subsequently granted PMA. Thus, this Court can conclusively resolve *in one decision* the scope of preemption as it relates to IDE Class III devices *and* PMA Class III devices, and thereby put an end to the growing number of conflicting lower court decisions.

The opportunity to resolve these unanswered questions *in one decision* will not likely present itself to this Court again. Therefore, this Court should grant SIMS' Petition for Writ of Certiorari.

III.

THE ILLINOIS APPELLATE COURT ERRONEOUSLY DEFINED THE SCOPE OF MDA PREEMPTION AS IT RELATES TO IDE AND PMA CLASS III MEDICAL DEVICES.

In opposition to SIMS' Petition, Plaintiffs do not dispute the existence of the conflict among the lower courts regarding MDA preemption. Nor do Plaintiffs dispute the legal and social importance of MDA preemption. Nor do Plaintiffs dispute that the CVS catheter in controversy was granted both an IDE and PMA.

Rather, in opposition to SIMS' Petition, Plaintiffs merely argue that the decision of the Illinois Appellate Court below was correct. As set forth below, however, Plaintiffs' arguments in that regard are erroneous.

In defending the Appellate Court's decision in *Kernats*, Plaintiffs have asserted arguments that were explicitly rejected *in the Kernats opinion*. For example, Plaintiffs argue that the MDA does not preempt their claims because there are no "specific" Federal requirements applicable to the SIMS CVS catheter. (Plaintiffs' Brief at 6). However, the Appellate Court in *Kernats* expressly held that the requirements of the premarket approval process *are* sufficiently specific to trigger preemption. (App. at 13).

Plaintiffs also argue that their claims are not preempted because MDA preemption applies only to legislatively enacted statutes and regulations, and was not intended to encompass state law tort claims. (Plaintiffs' Brief at 7). However, the Illinois Appellate Court in *Kernats* expressly rejected the argument that state tort law claims can never be preempted. (App. at 10). In fact, the Appellate Court in *Kernats* correctly held that in

Medtronic a majority of this Court's Justices held that the scope of MDA preemption *does* encompass state law tort claims. (App. at 10).

The basis of the *Kernats* decision—and the basic flaw in that decision—is the Appellate Court's conclusion that the Plaintiffs' claims of negligence, strict liability and failure to warn are not preempted because those claims arise from "general duties applicable to every manufacturer." (App. at 14). In reaching that conclusion, the Appellate Court erroneously relied on an isolated portion of the *Medtronic* opinion that was *rejected by a majority of this Court's Justices*.

Specifically, the Appellate Court in *Kernats* relied on a *single paragraph* of Section V of Justice Stevens' plurality decision in *Medtronic*, where Justice Stevens, writing for himself and only three other members of this Court, stated that the Lohrs' claims for negligent manufacturing and negligent failure to warn were not preempted because they "were not specifically developed 'with respect to' medical devices." *Medtronic*, 116 S.Ct. at 2258. There, Justice Stevens wrote as follows:

> The predicate for the Lohrs' negligent manufacturing claim is the general duty of every manufacturer to use due care to avoid foreseeable dangers in its products. Similarly, the predicate for the failure to warn claim is the general duty to inform users and purchasers of potentially dangerous items of the risks involved in their use. . . . These State requirements therefore escape preemption, not because the source of the duty is a judge-made or common-law rule, but rather because their generality leaves them outside the category of requirements that § 360k

> envisioned to be "with respect to" specific devices such as pacemakers.

Id.

Although the Appellate Court in *Kernats* relied on the foregoing passage from Justice Stevens' opinion, (App. 14-15), a close reading of the *Medtronic* opinion *in its entirety* reveals that a majority of this Court's Justices rejected Justice Stevens' view regarding the preemption of "general" common law duties. Writing for herself and three other Members of this Court, Justice O'Connor explicitly rejected Justice Stevens' view. *Id.* at 2262-64. In no uncertain terms, Justice O'Connor held that the Lohrs' "general" claims for negligent manufacturing and failure to warn *were* preempted. *Id.*

Justice Breyer, who wrote a separate opinion concurring in part and concurring in the judgment, broadly held that common law claims, *under certain circumstances*, may be preempted by the MDA. *Id.* at 2259. Justice Breyer then clarified that holding, explaining that common law claims are preempted only when there are "specific" *federal* requirements applicable to the medical device in controversy. *Id.* at 2260-61 (citing 21 C.F.R. §808.1(d)).

Significantly, Justice Breyer did *not* hold that preemption occurs only when the common law claims at issue are also device-specific. Rather, Justice Breyer held that the need for specificity applies only to the *federal* requirements at issue. *Id.* at 2261. Thus, unlike Justice Stevens, Justice Breyer did *not* hold that "general" state law requirements, such as those arising from common law negligence claims, escape preemption. In fact, Justice Breyer expressly held that a negligence claim brought

against a medical device manufacturer would be subject to preemption in the presence of a conflicting specific federal requirement. *Id.* at 2259.

Significantly, in the recent decision in *Papike v. Tambrands, Inc.*, 107 F.3d 737, 742 (9th Cir. February 20, 1997), the Ninth Circuit held that Justice Breyer *disagreed* with Justice Stevens' view regarding the preemption of generally applicable tort law claims. In *Papike*, the Ninth Circuit held that a "fair reading" of Justice Breyer's separate opinion reveals that Justice Breyer concluded that generally applicable tort law claims can be preempted. In that regard the Ninth Circuit held as follows:

> It makes little sense to argue that Justice Breyer would write separately to make clear his position that duties arising under state common law can constitute state law "requirements" which can be preempted by the MDA, and then agree that because tort law consists of generally applicable principles, it is always preempted, even in the face of specific federal requirements. Instead, in *Medtronic* Justice Breyer found "no actual conflict between any federal requirement and any of the liability-creating-premises of the plaintiffs' state law tort suit." (Citing *Medtronic* at 2261). Here, there would be such a conflict. Part of Papike's claim is that the federal requirements do not suffice, and that Tambrands should be required to, among other things, add a variety of warning statements not required by the federal regulation. As Justice Breyer explained, these are "the legal requirements that grow out of the application, in particular circumstances, of a State's tort law." (Citing *Medtronic* at 2259).

Papike at 742.

Thus, despite Justice Breyer's agreement with *certain* aspects of Justice Stevens' opinion, Justice Breyer clearly rejected Justice Stevens' view that the MDA does not preempt claims based on general common law duties. As stated above, four other Justices—comprising a majority of five Justices—also rejected Justice Stevens' "general duty" holding. Therefore, the Appellate Court in *Kernats* misapplied the *Medtronic* opinion by finding against preemption based on the general nature of the common law duties underlying the Plaintiffs' claims.

In summary, to *conclusively* resolve the sharp division among the lower courts regarding the scope of MDA preemption, to ensure the availability of life-saving and life-enhancing medical devices, and to correct the erroneous decision of the Appellate Court in *Kernats*, this Court should grant SIMS' Petition for Writ of Certiorari.

CONCLUSION

The petition for writ of certiorari should be granted.

Respectfully submitted,

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In the Supreme Court of the United States

OCTOBER TERM, 1997

SMITHS INDUSTRIES MEDICAL SYSTEMS, INC.,
PETITIONER

v.

SARAH KERNATS, ET AL.

ON PETITION FOR A WRIT OF CERTIORARI TO THE APPELLATE COURT OF ILLINOIS

BRIEF FOR THE UNITED STATES AS AMICUS CURIAE

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QUESTION PRESENTED

Whether the Medical Device Amendments of 1976 (MDA), which create a federal program for regulating medical devices and prohibit the States from imposing safety requirements that are "different from, or in addition to," federal requirements, 21 U.S.C. 360k(a), preempt a State's general common law remedies for injury from defective products.

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In the Supreme Court of the United States

OCTOBER TERM, 1997

No. 96-1405

SMITHS INDUSTRIES MEDICAL SYSTEMS, INC.,
PETITIONER

v.

SARAH KERNATS, ET AL.

ON PETITION FOR A WRIT OF CERTIORARI TO THE APPELLATE COURT OF ILLINOIS

BRIEF FOR THE UNITED STATES AS AMICUS CURIAE

This brief is filed in response to the Court's order inviting the Solicitor General to file a brief expressing the views of the United States.

STATEMENT

Petitioner seeks review of a decision of the intermediate Appellate Court of Illinois arising from three separate tort suits in which respondents allege that they were injured by a medical device manufactured by petitioner. Petitioner moved for summary judgment in each case on the ground that a federal statute, the Medical Device Amendments of 1976 (MDA), Pub. L. No. 94-295, 90 Stat. 539, preempts respondents' claims. The trial court in each case granted petitioner's motion for summary judgment. Pet. App. 25-32. The Appellate Court of Illinois consoli-

dated respondents' appeals, reversed the trial court judgments, and remanded the cases for trial. *Id.* at 1-19.

1. The Federal Food, Drug, and Cosmetic Act of 1938 (FDCA), 21 U.S.C. 301 *et seq.*, empowers the Food and Drug Administration (FDA) to regulate a wide variety of medical and non-medical products. The MDA supplements the FDCA's original provisions by creating a federal program to enhance "the safety and effectiveness of medical devices intended for human use" (90 Stat. 539 (Preamble)). See generally *Medtronic, Inc.* v. *Lohr*, 116 S. Ct. 2240, 2245-2246 (1996). The MDA authorizes the FDA to undertake specified review, approval, and regulatory activities for medical devices, which include instruments, implants, and similar articles that are intended to affect the structure or function of the body or for use in medical applications. See 21 U.S.C. 321(h) (defining "device"), 360c-360*l* (regulatory program).

a. The MDA provides for the classification of medical devices into three categories based on the risk that they pose to the public. 21 U.S.C. 360c(a). Class I devices are articles, such as tongue depressors and sunglasses, that present no unreasonable risk of illness or injury. See 21 C.F.R. 880.6230, 886.5850. The FDA subjects those devices to limited regulation through the use of "general controls," 21 U.S.C. 360c(a)(1)(A), which involve measures such as general labeling and manufacturing practices requirements. See, *e.g.*, 21 U.S.C. 352, 360j(f). Class II devices are articles, such as breathing frequency monitors and infusion pumps, for which "general controls by themselves are insufficient to provide reasonable assurance of the safety and effectiveness of the device." 21 U.S.C. 360c(a)(1)(B); see 21 C.F.R. 868.2375, 880.5725. The MDA subjects those devices to "special controls." 21 U.S.C. 360c(a)(1)(B). In the case of both Class I and Class II devices, the MDA does not require advance FDA approval before the device may be marketed. The maker usually

must comply, however, with the FDA's registration requirements and provide the agency with a "premarket notification" before distributing the device. See 21 U.S.C. 360(b) and (k).

Class III devices are articles, such as cardiac pacemakers and intraocular lenses, that present "a potential unreasonable risk of illness or injury." 21 U.S.C. 360c(a)(1)(C); see 21 C.F.R. 870.3610, 886.3600. In general, the makers of those articles are subject not only to general and certain special controls, but also to the FDA's "premarket approval" (PMA). See 21 U.S.C. 360c(a)(1)(C), 360e(a). An application for PMA must contain detailed supporting information, including full reports of any clinical investigations respecting the safety and effectiveness of the device, and a complete description of the device's components and method of manufacture. See 21 U.S.C. 360e(c). The FDA will approve the device unless it finds that the applicant has failed to provide reasonable assurance that the device is safe and effective for its intended use or that the applicant has failed to satisfy general manufacturing and labeling requirements. See 21 U.S.C. 360e(d); see also 21 C.F.R. Pt. 814.

b. The MDA provides that, in certain circumstances, a Class III device may be made available for use without obtaining a PMA. Of greatest practical importance, a maker may be entitled to postpone the PMA process if it proposes to market a Class III device that is substantially similar to a device that was on the market before the MDA's enactment and for which premarket approval is not required. The MDA contains a "grandfather" clause that allows continued marketing of devices that were on the market before the MDA's enactment until the FDA initiates and completes a rulemaking procedure requiring the submission of a PMA for the device. See 21 U.S.C. 360e(b)(1)(A). To prevent the "grandfathered" makers from monopolizing the market, the MDA provides

that other makers may distribute similar devices upon a showing through the general premarket notification process, 21 U.S.C. 360(k), that the devices are "substantially equivalent." 21 U.S.C. 360e(b)(1)(B). That procedure is known as the "Section 510(k) process," referring to the section of the FDCA codified at 21 U.S.C. 360(k). See *Medtronic*, 116 S. Ct. at 2247.

A maker may also defer the PMA process if it qualifies for an "Investigational Device Exemption" (IDE). Under that exemption, the FDA may approve an application for use of the device in clinical investigations to study its potential safety and effectiveness. See 21 U.S.C. 360j(g); 21 C.F.R. Pt. 812. Generally speaking, the FDA has provided by regulation that it may grant an IDE if it determines, based on the application, that the risks to the subjects of the investigations are outweighed by their anticipated benefits and the importance of the knowledge to be gained. 21 C.F.R. 812.30(b)(4).

c. The MDA contains a provision expressly addressing the question of preemption of state law. Section 521(a), 21 U.S.C. 360k(a), states:

> **(a) General rule**
>
> Except as otherwise provided in subsection (b) of this section, no State or political subdivision of a State may establish or continue in effect with respect to a device intended for human use any requirement—
>
> (1) which is different from, or in addition to, any requirement applicable under this chapter to the device, and
>
> (2) which relates to the safety or effectiveness of the device or to any other matter included in a requirement applicable to the device under this chapter.

Subsection (b) then provides that a State or political subdivision thereof may apply for an exemption for a require-

ment that would otherwise fall within the scope of Section 360k(a). See 21 U.S.C. 360k(b).

2. This Court addressed Section 360k's preemptive effect in *Medtronic*. The plaintiffs, husband and wife, alleged that the wife was injured by a defective pacemaker, a Class III device. The FDA had cleared the device for distribution on the basis, noted above, that the product was "substantially equivalent" to a pre-MDA device. The plaintiffs sought damages for their injuries under state tort law. They alleged that the manufacturer had negligently designed, built, and labeled the device and also sought recovery under a state law theory of strict product liability. The manufacturer contended that the MDA preempted the plaintiffs' claims because Section 360k prohibits a State from imposing a safety "requirement" that is "different from, or in addition to," any MDA requirement. The Court rejected the manufacturer's argument.[1]

a. At the outset of its analysis, the Court recognized the familiar presumption that the States retain their historic police powers unless Congress expresses a "clear and manifest purpose" to supersede those powers. *Medtronic*, 116 S. Ct. at 2250. The Court also acknowledged the "oft-repeated" observation that congressional purpose "is the ultimate touchstone" in every preemption case and that "a fair understanding of congressional purpose" may be discerned not only from the text of the statute, "but through the reviewing court's reasoned understanding of the way in which Congress intended the statute and its surrounding regulatory scheme to affect business, consumers, and the law." *Id.* at 2250-2251 (emphasis deleted).

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[1] Justice Stevens wrote an opinion in which Justices Kennedy, Souter, and Ginsburg joined in full. 116 S. Ct. at 2245-2259. Justice Breyer concurred in parts I through III, V, and VII of Justice Stevens' opinion and concurred in the judgment. *Id.* at 2259-2262. Justice O'Connor, joined by the Chief Justice and Justices Scalia and Thomas, concurred in part and dissented in part. *Id.* at 2262-2264.

b. Turning to the maker's specific arguments, the Court first evaluated whether Section 360k preempted state law claims alleging the manufacturer had defectively designed the pacemaker. 116 S. Ct. at 2254-2255. It noted that, while the MDA required the manufacturer to provide the FDA with premarket notification, and the FDA may have conducted the premarket notification process "with a concern for the safety and effectiveness of the device," the FDA "did not 'require' Medtronic's pacemaker to take any particular form for any particular reason." *Id.* at 2254. The Court accordingly concluded that the manufacturer's compliance with the PMA process "did not preempt the [plaintiffs'] design claims." *Id.* at 2255; accord *id.* at 2264 (O'Connor, J., concurring in part and dissenting in part) (Section 510(k) process "places no 'requirements' on a device" and therefore does not preempt defective design claim).

The Court next examined whether Section 360k preempted state law claims that the manufacturer had violated FDA requirements. 116 S. Ct. at 2255-2256. It concluded that state law claims premised on a violation of FDA requirements do not subject the manufacturer to requirements that are "different from, or in addition to," the federal requirements. *Id.* at 2255. The Court noted that the FDA's interpretive regulations "expressly support the conclusion that § 360k 'does not preempt State or local requirements that are equal to, or substantially identical to, requirements imposed by or under the act,'" *id.* at 2256 (quoting 21 C.F.R. 808.1(d)(2)), and it observed that the FDA's views on the scope of Section 360k's preemptive effect are entitled to "substantial weight," *ibid.*; see also *id.* at 2260-2261 (Breyer, J., concurring in part and concurring in the judgment).[2]

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[2] Justice O'Connor agreed with the majority that state law claims based on violations of federal requirements are not preempted, but

The Court also examined whether Section 360k preempted state law claims based on negligent manufacturing and labeling. 116 S. Ct. at 2256-2258. The Court recognized that the FDA had developed regulations that set out general "requirements" for manufacturing and labeling medical devices. *Id.* at 2256. It concluded, however, that Section 360k does not mandate preemption unless, as the FDA had suggested in its interpretive regulations, the federal requirements impose specific requirements on a particular medical device. *Id.* at 2257 (citing 21 C.F.R. 808.1(d)). The Court concluded that the "entirely generic" federal manufacturing and labeling requirements did not provide a basis for preemption of the non-specific state common law duties at issue in that case. *Id.* at 2258. In his separate opinion, Justice Breyer, agreeing with Justice O'Connor's opinion for four Justices (see *id.* at 2262-2263), concluded that, ordinarily, insofar as the MDA preempts a state requirement embodied in a state statute or regulation, it also preempts a similar state requirement that takes the form of a standard of care or behavior imposed by state tort law, *id.* at 2259-2260; but he concurred in the Court's holding that the federal manufacturing and labeling requirements were not sufficiently "specific" to trigger preemption, *id.* at 2260-2261.[3]

3. Petitioner manufactures and sells a "chorionic villus sampling" (CVS) catheter, a Class III device used to sample fetal tissue to detect genetic abnormalities during the early stages of pregnancy. From 1984 to 1990, petitioner made the CVS catheter available for use through an

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disagreed with the majority's reliance on the FDA regulations interpreting the Act's preemption provision. 116 S. Ct. at 2263, 2264.

[3] The separate opinion of Justice O'Connor did not agree with the majority's conclusion that, as construed in the FDA regulations, only "specific" federal requirements trigger preemption under Section 360k(a). See 116 S. Ct. at 2263, 2264.

exemption for use under the MDA's IDE provisions. In 1990, petitioner completed the PMA process. Pet. App. 2-3, 6 n.3. In the three cases at issue, respondents alleged that the CVS catheter had caused prenatal injuries and sought damages under state law theories of strict product liability, breach of express and implied warranties, and common law negligence. In two of those cases, the medical procedures took place while the IDE was in effect. In the third case, the medical procedure took place after petitioner had received the PMA. In all three cases, the district court granted petitioner's motion for summary judgment, concluding that, under Section 360k, the federal regulatory process had resulted in preemption of respondents' state law tort claims. *Id.* at 25-32.

The Appellate Court of Illinois consolidated respondents' appeals, reversed the judgments, and remanded the cases for trial. Pet. App. 1-19. The court recognized that "the facts in the present case are different from those in *Medtronic* because the medical device here underwent rigorous PMA scrutiny." *Id.* at 13. Although the court observed that this Court did not consider in *Medtronic* whether the PMA review process is sufficiently concrete so as to constitute a "specific" requirement having preemptive force, it held, following a number of pre-*Medtronic* appellate decisions, that the PMA process is a specific federal requirement. *Ibid.* The Court concluded, however, that the generic state law tort duties that petitioner had allegedly breached were not requirements specifically developed with respect to medical devices, and therefore were not preempted. *Id.* at 13-14.

The Appellate Court of Illinois explained its reasoning as follows:

> Here, [respondents'] common-law claims based on the manufacture of the CVS catheter, the failure to warn, and inadequate instructions, are also "general

> obligations" applicable to all manufacturers and, under the holding in *Medtronic*, are not requirements specifically established for medical devices. Therefore, they are not preempted under the MDA. [Respondents'] claims based on defective design and inadequate testing allege that defendant defectively designed and failed to adequately test the CVS catheter. Although these allegations relate to the specific medical device at issue here, they arise, nevertheless, from general duties applicable to every manufacturer.

Pet. App. 14. For similar reasons, the court rejected petitioner's argument that the MDA preempts state statutory law claims based on an implied warranty of merchantability and fitness. *Id.* at 16. It also rejected petitioner's assertion of preemption with respect to express warranty claims, noting that those claims are based on "[petitioner's] own express representations" and are not state "requirements" within the meaning of Section 360k. *Id.* at 18.

The Supreme Court of Illinois denied discretionary review. Pet. App. 20, 23.

DISCUSSION

Petitioner contends that the Appellate Court of Illinois has incorrectly applied this Court's decision in *Medtronic*, which interpreted the preemptive effect of Section 360k. As petitioner correctly points out, the state court's decision in this case involves an issue of substantial importance that has divided the lower courts. This Court's review is unwarranted, however, in this case. First, as a threshold matter, a proper jurisdictional basis is lacking because the judgment is not final within the meaning of 28 U.S.C. 1257. Second, although we disagree with the reasoning of the Appellate Court of Illinois, the judgment below is correct. Third, the FDA will publish for public comment a proposed interpretive rule on the statutory provision at issue. Because this Court's decision in

Medtronic is relatively recent, and the FDA is providing an interpretive rule on the subject, there is no urgent need for the Court to revisit the question of Section 360k's preemptive effect at this time.

1. This Court lacks jurisdiction to review the judgment of the Appellate Court of Illinois because that judgment is neither final in a strict sense nor included within one of the exceptions to strict finality recognized by this Court. Petitioner invokes this Court's jurisdiction under 28 U.S.C. 1257. By its terms, that provision encompasses "[f]inal judgments or decrees rendered by" state courts. Thus, as a general rule, interlocutory state court decisions are not reviewable under Section 1257, and state court rulings fall within the literal meaning of this provision only if they conclusively resolve the litigation and represent "the final word of a final court." *Jefferson* v. *City of Tarrant*, No. 96-957 (Dec. 9, 1997), slip op. 5; *Market St. Ry.* v. *Railroad Comm'n*, 324 U.S. 548, 551 (1945); see, *e.g.*, *Cox Broadcasting Corp.* v. *Cohn*, 420 U.S. 469, 476-487 (1975); *Urie* v. *Thompson*, 337 U.S. 163, 171-172 & n.10 (1949); see also Robert Stern, Eugene Gressman, Stephen Shapiro & Kenneth Geller, *Supreme Court Practice* 92-111 (7th ed. 1993).

The judgment of the Appellate Court of Illinois is not final in that strict sense. The court's interlocutory ruling reverses the trial courts' grants of summary judgment and remands for further proceedings. Petitioner may well prevail on some or all claims on remand. And if the ultimate result of the litigation is unfavorable to petitioner in any respect, petitioner may at that time seek review of the preemption issue in this Court, based on a more fully developed record and any further rulings by the state courts on preemption.

Adhering to the view that finality should be given "a 'practical rather than a technical construction,'" *Cox Broadcasting*, 420 U.S. at 478 n.7 (quoting *Cohen* v.

Beneficial Indus. Loan Corp., 337 U.S. 541, 546 (1949)), this Court has recognized four categories of cases that constitute exceptions to strict finality under 28 U.S.C. 1257. *Cox Broadcasting*, 420 U.S. at 476-487; *Duquesne Light Co.* v. *Barasch*, 488 U.S. 299, 306 (1989). The first three categories consist of situations, respectively, in which: (1) the federal issue is conclusive or the outcome on remand is pre-ordained; (2) the federal issue will survive and require decision regardless of the outcome of proceedings on remand; and (3) the federal issue cannot be reviewed after the conclusion of the proceedings on remand. *Cox Broadcasting*, 420 U.S. at 479-481. As in *Flynt* v. *Ohio*, 451 U.S. 619 (1981) (per curiam), "it is not even arguable that the judgment involved here falls within any of the first three categories identified in the *Cox* opinion." *Id.* at 621.

The fourth category consists of situations that satisfy two requirements. First, the state court judgment must represent the final word within the state court system on a federal issue, "with further proceedings pending in which the party seeking review here might prevail on the merits on nonfederal grounds, thus rendering unnecessary review of the federal issue by this Court, and where reversal of the state court on the federal issue would be preclusive of any further litigation on the relevant cause of action." *Cox Broadcasting*, 420 U.S. at 482-483. Second, "a refusal immediately to review the state-court decision" must risk "seriously erod[ing] federal policy." *Id.* at 483.

In the United States' view, the judgment of the Appellate Court of Illinois does not fall within the fourth *Cox* category. We may assume that, if the judgment petitioner seeks to have reviewed were the judgment of the Illinois Supreme Court, it would satisfy the first prong of the two-part test, because the federal issues would have been finally resolved (but see pages 17-18, *infra*) and because petitioner might prevail on remand by establish-

ing that it is not liable under the state law standard. Here, however, petitioner seeks review of the decision of an intermediate appellate court. That judgment may not represent the final word in the state court system on the preemption issue because, although the Illinois Supreme Court denied discretionary review at this interlocutory stage, it might later choose to grant review of the federal questions on appeal from a final judgment. But see *Belknap, Inc.* v. *Hale*, 463 U.S. 491, 497 n.5 (1983) (finding jurisdiction without specifically addressing status of judgment below as that of intermediate appellate court). There is no need to decide whether an intermediate state appellate court judgment is a "final judgment" for purposes of the fourth *Cox* exception, however, because petitioner falls short of establishing, under the second prong of the fourth exception, that postponing review will likely erode an important federal policy. In this case, an argument that the situation falls within the fourth category, "although not frivolous, is unsound." *Flynt*, 451 U.S. at 621.

This Court has most frequently found a potential erosion of federal policy when the state court ruling has restricted the exercise of a fundamental constitutional right.[4] This case, however, does not involve such a situation. The Court has also exercised jurisdiction when the state court ruling could undermine a federal statutory policy, particularly when the policy was furthered by restricting the forum in which the merits of a dispute

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[4] See *Fort Wayne Books, Inc.* v. *Indiana*, 489 U.S. 46, 54-56 (1989) (freedom of the press); *National Socialist Party of America* v. *Village of Skokie*, 432 U.S. 43, 44 (1977) (per curiam) (freedom of speech); *Cox Broadcasting*, 420 U.S. at 485-487 (freedom of the press); *Miami Herald Publishing Co.* v. *Tornillo*, 418 U.S. 241, 247 n.6 (1974) (same); *Calder* v. *Jones*, 465 U.S. 783, 788 n.8 (1984) (due process limitations on personal jurisdiction); *Shaffer* v. *Heitner*, 433 U.S. 186, 195 n.12 (1977) (same).

could be resolved.[5] This case, however, does not present a comparable threat to a congressional policy.

First, as this Court noted in *Medtronic*, the central purpose of the MDA is "to provide for the safety and effectiveness of medical devices intended for human use," 116 S. Ct. at 2245 (quoting 90 Stat. 539 (Preamble)), in order to "safeguard the health of the American public," H.R. Rep. No. 853, 94th Cong., 2d. Sess. 12 (1976). Allowing respondents' tort suits to proceed will in no way undermine that interest in protecting consumers and promoting public health. On the contrary, allowing the suits to go forward should, as a general matter, promote those very interests by deterring manufacturers from distributing defective or unreasonably dangerous medical devices.

Second, to the extent that Section 360k of the MDA expresses a federal policy to preempt state requirements respecting the safety and effectiveness of medical devices, that concern is "related more to the risk of *additional* federal and state regulation rather than the danger of preexisting duties under common law." *Medtronic*, 116 S. Ct. at 2253. There is no inherent conflict between regulation of devices by the FDA (including the IDE and PMA processes) and state law tort claims; the Federal Act does not establish a rule of primary jurisdiction to adjudicate individual disputes. Moreover, as we explain in greater detail below, Section 360k does not, on the present record, preempt respondents' common law tort claims. Accord-

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[5] See *Belknap*, 463 U.S. at 497 n.5 (resolving labor-management disputes before the NLRB); *Local No. 438 Construction & General Laborers' Union* v. *Curry*, 371 U.S. 542, 550 (1963) (same); *Southland Corp.* v. *Keating*, 465 U.S. 1, 6-8 (1984) (resolving contractual issue through arbitration under Federal Arbitration Act rather than through adjudication); *Mercantile Nat'l Bank* v. *Langdeau*, 371 U.S. 555, 557-558 (1963) (limiting venues within which suits against national banks may be brought).

ingly, allowing respondents' suits to proceed will not erode the federal policy expressed in the MDA.[6]

2. Petitioner asserts that, because it secured an IDE and PMA for the device at issue, it should not be subject to product liability claims under state law. That contention is incorrect. In the FDA's view, as reflected in its notice of proposed rulemaking for the issuance of an interpretive rule under Section 360k (see App., *infra*, 1a-18a), the agency's decision to grant an IDE and PMA for the device at issue here did not establish specific federal requirements within the meaning of Section 360k. Like its review of the premarket notification in *Medtronic*, the FDA's review in this case established only that the manufacturer had complied with the applicable federal minimum standards for use and marketing. As this Court indicated in *Medtronic*, Section 360k will generally result in preemption of state tort claims only if the federal government has imposed specific requirements on a particular medical device and the state common law imposes a requirement on the same device that is "different from, or in addition to," the federal requirement. See 116 S. Ct. at 2257-2258. In these circumstances, the Appellate Court of Illinois ruled, the general duties imposed by Illinois common law do not impose state requirements respecting the device at issue that are "different from, or in addition to," any specific federal requirement. Pet. App. 12-15.

a. The FDA's decision to grant an IDE or a PMA for a medical device does not, by itself, create specific federal requirements within the meaning of Section 360k. We therefore disagree with the Appellate Court on this point. See Pet. App. 13a.

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[6] Although this point reflects a view of the merits, this Court has long recognized that *Cox*'s fourth category frequently requires some inquiry into the merits of the underlying claims. See *Cox Broadcasting*, 420 U.S. at 486 n.13.

The FDA's grant of an IDE signifies that the FDA has examined the manufacturer's application and determined that the device meets the federal criteria for investigatory use. See 21 U.S.C. 360j(g). Similarly, the FDA's grant of a PMA signifies that the FDA has examined the manufacturer's application and determined that the device satisfies the federal criteria for marketing. See 21 U.S.C. 360e(d). The federal criteria are important, and the FDA conducts a careful inquiry to ensure compliance. See 21 C.F.R. Pts. 812 (IDE procedures), 814 (PMA procedures). But in the typical case, the federal criteria for IDEs and PMAs are the generally applicable threshold standards set out in the MDA and the FDA regulations. See 21 C.F.R. 812.30(b) (grounds for denying an IDE), 814.45 (grounds for denying a PMA). As in the case of the premarket notification, labeling, and manufacturing requirements in *Medtronic*, those general criteria establish minimum standards that do not displace state law standards of care or common law duties respecting the medical device.

The FDA may impose specific federal requirements for a Class III device, above and beyond the general federal criteria, that have preemptive force. For example, if the FDA determines that precise design, manufacturing, or labeling specifications are necessary to protect the public, it may impose such requirements through promulgation of specific regulations. See, *e.g.*, 21 C.F.R. 861.1(b)(3) (providing for mandatory performance standards for Class III devices). A manufacturer that seeks an IDE or PMA must satisfy those specific requirements, but they exist independently of the IDE and PMA processes. We have been informed by the FDA that it imposes such specific requirements on Class III devices only in extraordinary situations, and only after it has considered the preemptive consequences of its action under Section 360k. See *Medtronic*, 116 S. Ct. at 2260 (Breyer, J., concurring in part and concurring in the judgment) (the FDA must

consider "the likely impact of both state and federal requirements").

The FDA's differentiation between agency review under the general IDE and PMA criteria and agency imposition of specific substantive requirements reflects its sensible and long-standing approach to regulating medical devices. Under the regulatory scheme, a manufacturer is responsible for submitting an application demonstrating that the proposed medical device satisfies federal minimum standards. See, *e.g.*, 21 C.F.R. Pts. 812, 814. If (as in this case) the FDA has not set out specific federal requirements for the particular device, the manufacturer may select any design, manufacturing, and labeling features that will satisfy the general minimum standards in the Act and regulations, and it may obtain an IDE or PMA on the basis of that selection if the FDA approves the application. Because the FDA has not imposed any specific substantive requirements on petitioner's design of the CVS in the course of the review process, that design does not represent a specific federal requirement that preempts state common law requirements. Cf. *American Airlines, Inc.* v. *Wolens*, 513 U.S. 219, 229 (1995). But if the FDA sets out specific requirements for the particular device in the future, the manufacturer must also satisfy those requirements, which would then preempt any different or additional state requirements.

The FDA's distinction between its review under federal minimum standards and its imposition of specific substantive requirements is consistent with the MDA's underlying objective of promoting safe and effective medical devices. For example, the FDA's grant of a PMA under the statutory criteria provides assurance, but not a guarantee, that the device is safe and effective for its specified use. Where the FDA has taken no further action, the States are entitled to exercise their historic police powers to provide their citizens with additional protec-

tion through positive enactments or through imposition of common law duties. But where the FDA has specifically identified a need to supplement the generalized minimum standards in the Federal Act and FDA regulations with additional federal requirements respecting the particular device, those specific requirements should supplant any state requirements that are "different from, or in addition to," the federal requirements. That approach respects the MDA's "overarching concern that pre-emption occur only where a particular state requirement threatens to interfere with a specific federal interest." *Medtronic*, 116 S. Ct. at 2257.

b. Section 360k is also inapplicable in the circumstances of this case because petitioner has not shown that Illinois common law imposes a substantive requirement specifically with respect to the medical device at issue here.[7] State courts can, of course, refine common law duties in a way that actually imposes specific requirements respecting a particular medical device. For example, a state court could provide, through its rulings or jury instructions, that a particular design feature breaches a common law duty. See *Medtronic*, 116 S. Ct. at 2259 (Breyer, J., concurring in part and concurring in the judgment). But the Illinois courts thus far have not done so in this case, and there accordingly would be no basis at this point for holding that Section 360k necessarily preempts state common law in this case—even if, contrary to our submission in point 2.a, the FDA had imposed a "specific" counterpart requirement with respect to the device. Indeed, the fact that the state courts, in the course

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[7] The same reasoning holds true with respect to respondents' claims that petitioner breached an implied warranty of merchantability under state law. Pet. App. 16. With respect to claims based on any express warranties, the manufacturer's obligations arise from its "express representations, not by a state-imposed duty." *Id.* at 18. They do not involve state "requirements" at all. *Ibid.*

of further proceedings, can refine state common law duties in light of experience and the circumstances of the particular cases, allows those courts to avoid creating conflicts between federal and state requirements that would lead to preemption.

3. As petitioner correctly notes, the lower courts, both state and federal, have not reached a consensus on questions concerning Section 360k's preemption of state common or statutory law applied in tort suits. See Pet. 7-10.[8] The current division among the lower courts on that issue would normally provide a strong justification for this Court to grant review and definitively resolve the conflict. The jurisdictional obstacle noted above (see pages 10-14, *supra*) would, in our view, prevent the Court from taking that action in this case. But even in the absence of that obstacle, we believe that it would be appropriate for the Court to defer review in light of the

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[8] See also, *e.g.*, *Mitchell* v. *Collagen Corp.*, 126 F.3d 902 (7th Cir. 1997) (preemption of state law claims respecting a device that received a PMA); *Oja* v. *Howmedica, Inc.*, 111 F.3d 782 (10th Cir. 1997) (preemption of state law claims respecting a Class II medical device); *Chambers* v. *Osteonics Corp.*, 109 F.3d 1243 (7th Cir.) (partial preemption of state law claims respecting a device that received an IDE); *Papike* v. *Tambrands, Inc.*, 107 F.3d 737 (9th Cir.) (preemption of state law claims respecting a device that received a PMA), cert. denied, 118 S. Ct. 166 (1997); *Martin* v. *Telectronics Pacing Systems, Inc.*, 105 F.3d 1090 (6th Cir. 1997) (preemption of state law claims respecting a device that received an IDE), petition for cert. pending, No. 96-1749 (filed May 1, 1997); *Fry* v. *Allergan Medical Optics*, 695 A.2d 511 (R.I.) (preemption of state law claims respecting a device that received a PMA), cert. denied, 118 S. Ct. 374 (1997); *Fiore* v. *Collagen Corp.*, 930 P.2d 477 (Ct. App. 1996) (no preemption of state law claims respecting a device that received a PMA), review denied, No. CV-96-0447-PR (Ariz. Jan. 14, 1997), petition for cert. pending, No. 96-1611 (filed Apr. 10, 1997); *Eddy* v. *Polymer Technology Corp.*, 674 A.2d 323 (Super. Ct. 1995) (Table) (preemption of state law claims), appeal denied, 692 A.2d 566 (Pa. 1997) (Table), petition for cert. pending, No. 97-26 (filed June 30, 1997).

FDA's recent initiative to provide an interpretive rule on Section 360k's preemptive effect.

This Court concluded in *Medtronic* that the FDA's views should be given "substantial weight" in determining the reach of the MDA's preemption clause. 116 S. Ct. at 2256. As the Court explained, "Congress has given the FDA a unique role in determining the scope of § 360k's pre-emptive effect," because "in most cases a state law will be pre-empted only to the extent that the FDA has promulgated a relevant federal 'requirement.'" *Id.* at 2255. "Because the FDA is the federal agency to which Congress has delegated its authority to implement the provisions of the Act, the agency is uniquely qualified to determine whether a particular form of state law 'stands as an obstacle to the accomplishment and execution of the full purposes and objectives of Congress.'" *Ibid.* (footnote omitted) (quoting *Hines* v. *Davidowitz*, 312 U.S. 52, 67 (1941)); see also *id.* at 2260-2261 (Breyer, J., concurring in part and concurring in the judgment).

The FDA will issue, for notice and comment, a proposed interpretive rule providing guidance on Section 360k's preemptive effect with respect to product liability claims under state law. That proposed rule explains that, as a general matter, a state common law duty is preempted only when: (1) the FDA has expressly imposed, by regulation or order, a specific substantive requirement applicable to a particular medical device; and (2) state common law imposes a substantive requirement applicable to the same medical device that is different from, or in addition to, the FDA's counterpart requirement. See App., *infra*, 1a-18a.

Under the FDA's interpretation, MDA minimum standards that are generally applicable to medical devices will typically not result in preemption of state tort claims. Accordingly, the FDA's grant of an IDE or a PMA does not, by itself, have preemptive effect. If the FDA imposes,

however, a substantive requirement for a particular medical device (such as a mandatory standard of performance, see 21 C.F.R. 861.1), that requirement would preempt a specific substantive requirement imposed by state statute, regulation, or common law (as interpreted and applied) that is "different from, or in addition to," the federal requirement. 21 U.S.C. 360k(a).

The FDA will publish its interpretive regulation for notice and comment on December 12, 1997, and it may modify and refine it in response to public comment before issuing it in final form. Furthermore, although the FDA's guidance is entitled to "substantial weight," it will not bind the lower courts. Nevertheless, the FDA's regulation is likely to focus the judicial inquiry and reduce the current uncertainty respecting Section 360k's preemptive effect. We therefore suggest that the Court should allow the lower courts to consider the scope of Section 360k in light of the FDA's regulation before the Court undertakes review of issues that it left open in *Medtronic*.[9]

CONCLUSION

The petition for a writ of certiorari should be denied.

Respectfully submitted.

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DECEMBER 1997

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[9] The President recently signed amendments to the FDCA that, *inter alia*, expedite the process for reviewing and approving PMA and IDE applications. See Food and Drug Administration Modernization Act of 1997, Pub. L. No. 105-115, §§ 201, 209, 111 Stat. 2296. Those amendments make no changes to the MDA's preemption provision.

APPENDIX

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 808

[Docket No. 97N-0222]

Medical Devices; Preemption of State Product Liability Claims

AGENCY: Food and Drug Administration, HHS.

ACTION: Proposed rule.

SUMMARY: The Food and Drug Administration (FDA) is proposing to amend its regulations regarding preemption of State and local requirements applicable to medical devices. This action is being taken to clarify and codify the agency's longstanding position that available legal remedies, including State common law tort claims, generally are not preempted under the Federal Food, Drug, and Cosmetic Act (the act).

DATES: Written comments by (*insert 60 days after date of publication in* **Federal Register**).

ADDRESSES: Submit written comments to the Dockets Management Branch (HFA-305), Food and Drug Administration, 12420 Parklawn Dr., rm 1-23, Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT: Joseph M. Sheehan, Center for Devices and Radiological Health

(HFZ-215), Food and Drug Administration, 2094 Gaither Rd., Rockville, MD 20850, 301-827-2974.

SUPPLEMENTARY INFORMATION:

I. Introduction

Section 521 of the act (21 U.S.C. 360k) contains an express preemption provision applicable to medical devices regulated by FDA. The Supreme Court recently addressed whether section 521 of the act preempts State common law tort claims arising from allegedly defective medical devices. (See *Medtronic, Inc.* v. *Lohr (Lohr)*, 116 S. Ct. 2240 (1996).) The Court concluded that section 521 of the act did not supplant the State law duties at issue in that case. In reaching that conclusion, the Court noted that FDA has provided interpretive guidance with respect to section 521 of the act's preemptive effect. (See *id.* at 2255-2256 (citing 21 CFR 808.1(d)(2) and 808.5(b)(1)(i) (1995)).) The Court gave "substantial weight to the agency's view of the statute" (*Id.* at 2256). (See also *id.* at 2257; *id.* at 2260-2261 (Breyer, J., concurring in part and concurring in the judgment).)

The Court's decision in *Lohr* construed section 521 of the act in the context of a medical device that FDA had cleared for distribution under section 510(k) of the act (21 U.S.C. 360k), which requires premarket notification for certain types of medical devices. The Court did not definitively decide whether section 521 of the act may preempt State law claims in other circumstances. Since *Lohr* was decided, the lower courts have interpreted section 521 of the act inconsistently and have reached conflicting conclusions with respect to whether section 521 of the act preempts State law claims for injuries allegedly resulting from medical devices that have received premarket approval under section 515 of the act (21 U.S.C. 360e), or have

received an investigational device exemption (IDE) under section 520(g) of the act (21 U.S.C. 360j(g)).

In light of the confusion among the lower courts in interpreting section 521 of the act since *Lohr*, and in accordance with the Supreme Court's recognition that FDA's interpretation of the preemptive effect of section 521 of the act is entitled to substantial weight, the agency is issuing this proposed interpretive rule, which addresses the circumstances in which section 521 of the act preempts State common tort claims based on injury from allegedly defective medical devices.

II. Background

Congress enacted the Medical Device Amendments of 1976 (the amendments) (21 U.S.C. 360c *et seq.*) "to provide for the safety and effectiveness of medical devices intended for human use." It enacted the amendments largely in response to public concerns over injuries caused by medical products, such as the Dalkon Shield intrauterine device. (See S. Rept. No. 33, 94th Cong., 1st sess. 1 (1975); H. R. Rept. No. 853, 94th Cong., 2d sess. 8 (1976); 122 Congressional Record 13,779 (1976)). Congress sought "to assure that the public is protected from unsafe and ineffective medical devices, that health professionals have more confidence in the devices they use or prescribe, and that innovations in medical device technology are not stifled by unnecessary restrictions" (H. R. Rept. No. 853, *supra*, at 12).

Section 521 of the act was included as part of the amendments, and generally states that except as provided in section 521(b) of the act no State or political subdivision of a State may establish or continue in effect with respect to a device intended for human use any requirement which is different from, or in addition to, any Federal requirement

applicable to the device, and which relates to the safety or effectiveness of the device or to any other matter included in a Federal requirement applicable to the device.

Section 521(b) sets forth the requirements if a political subdivision thereof applies for an exemption from a Federal requirement. The Secretary may issue a regulation to exempt from section 521(a) of the act, under conditions prescribed in the regulation, if the requirement is more stringent than the Federal requirement which would be applicable to the device if an exemption were not in effect or the requirement is required by compelling local conditions, and compliance with the requirement would not cause the device to be in violation of any applicable Federal requirement under this chapter.

FDA has interpreted the preemptive scope of section 521 of the act in light of its specific language and Congress's expressed objectives. Section 521(a) forbids a State from subjecting a medical device to any "requirement" that is "different from, or in addition to," any Federal requirement imposed under the act; and relates to "the safety or effectiveness of the device" or to "any other matter" included in the Federal requirement. FDA has indicated, through regulations that have been in place since 1978, that section 521 of the act's preemptive effect is limited in light of the section's precise terminology and Congress's declared intention to promote the safety and effectiveness of medical devices. (See 21 CFR 808.1.)

When FDA issued its 1978 regulations, the regulated community was primarily interested in the effect of section 521 of the act on State or local requirements that were expressed through positive enactments, such as statutes or regulations. FDA's regulations addressed the question of preemption in that general context. Section 808.1(d), which has remained substantially unchanged for

nearly 20 years, states that State or local requirements are preempted only when FDA has established specific counterpart regulations or there are other specific requirements applicable to a particular device under the act, thereby making any existing divergent State or local requirements applicable to the device different from, or in addition to, the specific FDA requirements. There are other State or local requirements that affect devices that are not preempted by section 521(a) of the act because they are not "requirements applicable to a device" within the meaning of section 521(a) of the act.

FDA's regulations (§ 808.1) provide nine examples of State or local provisions that are not preempted, including:

(1) Generally applicable requirements not limited to medical devices (e.g., general electrical codes and the Uniform Commercial Code (warranty of fitness));

(2) Requirements that are equal to or substantially identical to requirements imposed by or under the act;

(3) Occupational licensing requirements;

(4) Specifications in government contracts for the procurement of devices;

(5) Criteria for payment of State or local obligations under Medicaid and similar Federal, State or local health care programs;

(6) General enforcement requirements, including State inspection and registration requirements, or a State or local prohibition against the manufacturer of adulterated or misbranded devices (except where the prohibition, as interpreted and enforced, has the effect of establishing a substantive requirement for a specific device);

(7) Provisions respecting delegations of authority and related administrative matters respecting devices;

(8) Fee and other revenue raising requirements; and

(9) State or local requirements issued under the authority of other Federal statutes.

In 1992, the Supreme Court decided *Cippolone* v. *Liggett Group, Inc.* (505 U.S. 504 (1992)). Among other things, the Court ruled in that case that section 5(b) of the Public Health Cigarette Smoking Act of 1969 (15 U.S.C. 1334(b)) could preempt State common law suits alleging that the manufacturers breached their duty to warn about hazards associated with smoking. Section 5(b) states that no requirement or prohibition based on smoking and health shall be imposed under State law with respect to the advertising or promotion of any cigarettes the packages of which are labeled in conformity with the provisions of this chapter.

A majority of the Supreme Court concluded that the phrase "[n]o requirement or prohibition," as used in that statute, describes both positive enactments and common law duties. (See 505 U.S. at 521 (opinion of Stevens, J.); *id.* at 548-549 (Scalia, J., concurring in the judgment in part and dissenting in part).)

After the Supreme Court's decision in *Cippolone*, a number of lower courts interpreted section 521 of the act to preempt tort actions respecting allegedly defective medical devices in which the plaintiff sought to hold the manufacturer liable based on State common law. Those courts found preemption in a variety of contexts, including situations in which FDA had allowed marketing of the device after "premarket notification" under section 510(k) of the act (21 U.S.C. 360(k)), (e.g., *Mendes* v. *Medtronic, Inc.*, 18 F.3d 13 (1st Cir. 1994)); in which FDA had granted premarket approval of the device under section 515 of the act (21 U.S.C. 360e), (e.g., *King* v. *Collagen Corp.*, 983 F.2d

1130 (1st Cir.) *cert. denied*, 510 U.S. 824 (1993)); and in which FDA had granted an IDE under section 520(g) of the act (21 U.S.C. 360j(g)), (e.g., *Slater* v. *Optical Radiation Corp.*, 961 F.2d 1330 (7th Cir.), *cert. denied*, 506 U.S. 917 (1992)).

The Supreme Court addressed the scope of section 521 of the act's preemptive effect in *Medtronic, Inc.* v. *Lohr*, 116 S. Ct. 2240 (1996). That case arose out of Medtronic's marketing of a cardiac pacemaker that FDA found was "substantially equivalent" to a medical device already on the market and that was therefore subject to the premarket notification requirements of section 510(k) of the act (21 U.S.C. 360(k)). The plaintiffs alleged that they were injured by the device and sought damages under Florida common law. They asserted that Medtronic breached its common law duty "to use reasonable care in the design, manufacture, assembly, and sale of the subject pacemaker" and that Medtronic was strictly liable because the device "was in a defective condition and unreasonably dangerous to foreseeable users at the time of its sale" (116 S. Ct. at 2248).

The Court concluded that section 521 of the act did not preempt the plaintiffs' negligent design claim. It specifically rejected Medtronic's contention that the company's compliance with its statutory obligation to demonstrate through the premarket notification process that the pacemaker was "substantially equivalent" to a preexisting device preempted those claims (116 S. Ct. at 2254-2255). The Court noted that, when FDA reviews a device under the premarket notification provisions, it does so with "a concern for the safety and effectiveness of the device" (*id.* at 2254), but that FDA "did not 'require' Medtronics' pacemaker to take any particular form for any particular reason" (*ibid*). Rather, FDA simply allowed Medtronic

to market the pacemaker based on the article's equivalence to the preexisting device (*Id.* at 2254-2255). The Supreme Court was unanimous on this point, since Justice O'Connor's separate opinion for four Justices agreed that the section 510(k) premarket notification process "places no 'requirement' on a device" and therefore does not preempt a defective design claim (*Id.* at 2264).

The Court also concluded that section 521 of the act did not preempt the plaintiffs' State law claims that Medtronic had violated FDA requirements (116 S. Ct. at 2255-2256). The Court reasoned that State common law claims premised on Medtronic's failure to comply with FDA requirements do not subject the manufacturer to requirements that are "different from, or in addition to," the Federal requirements (*Id.* at 2255). The Court noted that FDA's interpretive regulations "expressly support the conclusion that [section 521] 'does not preempt State or local requirements that are equal to, or substantially identical to, requirements imposed by or under the act.'" (*Id.* at 2256 (quoting 21 CFR 808.1(d)(2) (1995))). It also observed that FDA's views on the scope of section 521 of the act's preemptive effect are entitled to "substantial weight." (*Ibid*).

The Court additionally concluded that section 521 of the act did not preempt the plaintiffs' State law claims based on negligent manufacturing and labeling (116 S. Ct. at 2256-2258). The Court recognized that FDA had developed regulations that set out general "requirements" for manufacturing and labeling medical devices (*Id.* at 2256). It concluded, however, that section 521 generally does not mandate preemption of a standard of care under State common law unless, as FDA had suggested in its interpretive regulations, FDA has issued "specific counterpart regulations or * * * other specific requirements

applicable to a particular device" (*Id.* at 2257 (quoting 21 CFR 808.1(d) (1995))). The Court concluded that the "entirely generic" Federal requirements did not provide a basis for preemption of the nonspecific State common law duties at issue in that case (*Id.* at 2258). Justice Breyer, agreeing with Justice O'Connor's opinion (see *id.* at 2262-2263), concluded that, insofar as the act preempts a State requirement embodied in a statute or regulation, it also preempts a similar State requirement that takes the form of a standard of care imposed by State tort law (*id.* at 2259-2260) but he concurred in the Court's holding that manufacturing and labeling requirements issued by FDA were not sufficiently specific to trigger preemption (*id.* at 2260-2261).

Since the Supreme Court's decision in *Lohr*, the lower courts have continued to reach contradictory determinations respecting section 521 of the act's preemptive effect, particularly as it relates to medical devices that have received premarket approval or an investigatory device exemption. Compare, e.g., *Fry* v. *Allergan Medical Optics*, 695 A.2d 511 (R.I. 1997) (finding preemption), *cert. denied*, No. 97-513 (U.S. Sup. Ct., Nov. 3, 1997) with *Kernats* v. *Smiths Indus. Med. Sys., Inc.*, 669 N.E. 2d 1300 (Ill. App. Ct.) (finding no preemption), *appeal denied*, 675 N.E.2d (Ill. 1996), *petition for cert. pending*, No. 96-1405 (U.S. Sup. Ct., filed Mar. 4. 1997).

III. The Proposed Rule

FDA interprets section 521 of the act's preemptive effect on the basis of congressional intent. As the Supreme Court stated in *Lohr*, congressional purpose "is the ultimate touchstone" in every preemption case, and "a fair understanding of congressional purpose" may be discerned not only from the text of the statute, but also through a "reasoned understanding of the way in which Congress

intended the statute and its surrounding regulatory scheme to affect business, consumers, and the law" (116 S. Ct. at 2250-2251 (emphasis deleted)). In addition, the statutory text must be read in light of established presumptions respecting preemption. As the Supreme Court stated in *Lohr*, the States are presumed to retain their historic police powers unless Congress expresses a "clear and manifest purpose" to supersede those powers (*Id.* at 2250).

Section 521 of the act does not, as a general matter, prevent a party who is injured by a defective medical device from seeking redress under a State's common law. Rather, section 521(a) of the act provides that a State may not "establish or continue in effect with respect to a device" a "requirement" that is "different from, or in addition to," a "requirement applicable under this chapter to the device" that "relates to the safety or effectiveness of the device" or to "any other matter included in" the Federal requirement (21 U.S.C. 360k(a)). By its plain terms, section 521 of the act does not prevent a State from imposing common law duties on manufacturers of medical devices unless those duties are "requirements" of the kind described in the statute.

When FDA articulated its understanding of section 521 of the act in its 1978 regulations, it stated the general rule to be that "State or local requirements are preempted only when the agency has established specific counterpart regulations or there are other specific requirements applicable to a particular device under the act, thereby making any existing divergent State or local requirements applicable to the device different from, or in addition to, the specific Food and Drug Administration requirements" (§ 808.1(d)). The Supreme Court explicitly endorsed FDA's position in the *Lohr* decision. (See 116 S.

Ct. at 2257; *id.* at 2260-2261 (Breyer, J., concurring in part and concurring in the judgment)). Similarly, the 1978 regulations provide that section 521 of the act does not preempt a State or local requirement prohibiting the manufacture of adulterated or misbranded devices, but that where such a prohibition, as "interpreted and enforced by the State and local government," "has the effect of establishing a substantive requirement for a specific device, e.g., a specific labeling requirement," it will be preempted if it is different from, or in addition to, a specific requirement established by FDA for the device (§ 808.1(d)(6)(ii)).

In 1978, FDA stated its understanding of section 521 of the act in the general context of State requirements that are imposed through positive law, such as statutes or regulations. The same principles should govern, however, in the case of State requirements that are imposed through the common law. FDA has consistently concluded that the same principles govern when it has addressed the question of preemption through its regulations, advisory opinions, and its judicial filings as amicus curiae. The Supreme Court implicitly endorsed that conclusion in the *Lohr* decision by applying the principles that FDA has announced in its 1978 regulations to the Lohrs' common law suit (See 116 S. Ct. at 2255-2256, 2257-2258; *id.* at 2260-2261 (Breyer, J., concurring in part and concurring in the judgment in part)).

In accordance with the principles that FDA articulated in its 1978 regulations, to which the Supreme Court in *Lohr* held that deference is owed, FDA believes that, as a general matter, an FDA-imposed requirement will preempt a State common law duty only when: (1) FDA has expressly imposed, by regulation or order, a specific substantive requirement applicable to a particular medical

device; and (2) the State common law, as interpreted and applied, imposes a substantive requirement applicable to the same particular medical device that is different from, or in addition to, FDA's counterpart requirement. Under this approach, FDA requirements that are applicable to devices in general, or that are established by means other than through regulation or order, should generally not result in preemption of State tort claims.

FDA bases its interpretation primarily on the language of section 521 of the act and the agency's past regulatory interpretation set out in § 808.1. In addition, a plurality of the Court noted in *Lohr* that there is no indication in the legislative history of the amendments that Congress intended to make a "dramatic change" in the availability of State common law remedies (*Id.* at 2253 n.13 (opinion of Stevens, J.)). The legislative history indicates that Congress was aware of ongoing product liability suits involving medical devices, but it contains no indication that Congress intended that the amendments would preempt those suits. See, e.g., S. Rept. No. 33, *supra*, at 1; H. R. Rept. No. 853, *supra*, at 8; 121 Congressional Record 10,688 (1975) (Sen. Kennedy); *id.* at 10,689 (Sen. Nelson); 122 Congressional Record 5850 (1976) (Rep. Abzug).

FDA's interpretation is also founded in its experience and understanding gained through implementing the amendments. FDA believes that its general regulatory review and approval processes provide a significant measure of protection against the marketing of dangerous or defective medical devices. FDA does not believe, however, that those processes can guarantee the safety of such devices. Accordingly, compliance with general FDA requirements should not broadly preempt State common law remedies, which provide an important (and frequently the

only) mechanism for persons to seek redress for injuries resulting from defective medical devices. FDA notes below several situations in which the agency's regulatory activities will typically not preempt State law remedies.

First, FDA's general clearance and approval processes, such as the clearance for marketing under section 510(k) of the act; the grant premarket approval under section 515 of the act; or the grant of an IDE under section 520(g) of the act, do not, by themselves, preempt State common law claims. Section 521 of the act provides for preemption of a State common law duty only if it imposes a requirement that is different from, or in addition to, a specific substantive requirement pertaining to the particular device that has been imposed by or under the act. FDA's action in clearing a product for marketing or granting an application for a PMA or an IDE signifies that the manufacturer's proposal for marketing or use of the device in question satisfies the relevant statutory and regulatory criteria for the clearance, approval, or exemption. It does not signify, however, that Congress or FDA has established a specific Federal requirement (e.g., with respect to the design of the device) that supplants a State common law duty.

Second, FDA's notification of deficiencies in, or proposal of modifications to, an application for a PMA or an IDE does not, as a general matter, create specific Federal requirements that have preemptive effect. Under FDA's approval and exemption programs, the applicant bears responsibility for preparing an acceptable application. FDA may notify the applicant of deficiencies and propose modifications to ensure that the applicant has satisfied the minimum standards for FDA approval or exemption, but those actions do not relieve the applicant of its ultimate responsibility for proposing the design, manufacturing,

and labeling of the device. For purposes of preemption analysis, the applicant who modifies an application in response to an agency notification of deficiency or proposal for modification has simply achieved the same status as an applicant who had submitted a satisfactory application at the outset.

Third, as the Supreme Court concluded in *Lohr*, FDA's general requirements respecting labeling (21 CFR 801.1 through 801.16), and good manufacturing practices (21 CFR 820.1 through 820.198), do not preempt State requirements, because the general Federal requirements do not pertain to specific devices. (See *Lohr*, 116 S. Ct. at 2256-2258). The same controlling principle applies whether the device subject to those requirements is a "grandfathered" device that was marketed before the enactment of the amendments, received FDA clearance for marketing under section 510(k) of the act, received a PMA under section 515 of the act, or received an IDE under section 520(g) of the act.

Fourth, even if FDA has imposed specific Federal requirements respecting a particular medical device, those requirements do not preempt all State common law claims respecting the device. Section 521 of the act provides for preemption only if the State common law duties are "different from, or in addition to," the specific Federal requirements. In many cases, preemption will depend on the plaintiff's precise legal claims and theories of recovery. For example, as the Supreme Court noted in *Lohr*, if the State common law required the manufacturer to comply with the Federal requirements, section 521 of the act would not preempt that duty (116 S. Ct. at 2255-2256). Furthermore, the courts may be able to reconcile an apparent conflict between Federal and State requirements by, for example, carefully formulating jury instructions to

limit the bases for liability to substantive standards of care that are consistent with any specific requirement that FDA has made applicable to the device.

In every case, section 521 of the act's preemptive effect should be evaluated in light of the statute's precise terms. As the Supreme Court noted in *Lohr*, section 521 of the act and FDA's regulations "require a careful comparison between the allegedly preempting Federal requirement and the allegedly preempted State requirement to determine whether they fall within the intended preemptive scope of the statute and regulations" (116 S. Ct. at 2257-2258). The outcome of particular cases will frequently depend on the character and circumstances of the particular state law claim. FDA will continue to monitor the development of the law in this area and provide additional guidance as the need arises.

This proposed rule would make no change in the agency's prior or current construction of the scope of section 521 of the act. Rather, the rule would simply clarify and codify the agency's longstanding interpretation of the scope of section 521 of the act as generally not preempting available legal remedies, including State common law tort claims.

IV. Environmental Impact

The agency has determined under 21 CFR 25.34(b) that this action is of a type that does not individually or cumulatively have a significant effect on the human environment. Therefore, neither an environmental assessment nor an environmental impact statement is required.

V. Analysis of Impacts

FDA has examined the impacts of the proposed rule under Executive Order 12866 and the Regulatory Flexibility Act (5 U.S.C. 601-612). Executive Order 12866 directs agencies to assess all costs and benefits of available regulatory alternatives and, when regulation is necessary, to select regulatory approaches that maximize net benefits (including potential economic, environmental, public health and safety, and other advantages; distributive impacts; and equity). The agency believes that this proposed rule is consistent with the regulatory philosophy and principles identified in the Executive Order. In addition, the proposed rule is not a significant regulatory action defined by the Executive Order and so is not subject to review under the Executive Order.

The Regulatory Flexibility Act requires agencies to analyze regulatory options that would minimize any significant impact of a rule on small entities. Because this rule only interprets the statute and does not establish any requirements, the agency certifies that this proposed rule will not have a significant impact on a substantial number of small entities. Therefore, under the Regulatory Flexibility Act, no further analysis is required.

VI. Request for Comments

Interested persons may, on or before (*insert date 60 days after date of publication in the* **Federal Register**), submit to the Dockets Management Branch (address above) written comments regarding this proposal. Two copies of any comments are to be submitted, except that individuals may submit one copy. Comments are to be identified with the docket number found in brackets in the heading of this document. Received comments may be

seen in the office above between 9 a.m. and 4 p.m., Monday through Friday.

List of Subjects in 21 CFR Part 808

Intergovernmental relations, Medical devices.

Therefore, under the Federal Food, Drug, and Cosmetic Act and under authority delegated to the Commissioner of Food and Drugs, it is proposed that 21 CFR part 808 be amended as follows:

PART 808—EXEMPTIONS FROM FEDERAL PREEMPTION OF STATE AND LOCAL MEDICAL DEVICES REQUIREMENTS

1. The authority citation for 21 CFR part 808 continues to read as follows:

Authority: 21 U.S.C. 360j, 360k, 371.

2. Section 808.1 is amended by adding new paragraphs (d)(11) and (d)(12) to read as follows:

§ 808.1 Scope.

* * * * *

(d) * * *

(11)(i) An FDA imposed requirement will preempt a State common law duty only when:

(A) FDA has expressly imposed, by regulation or order, a specific substantive requirement applicable to a particular device; and

(B) The State common law, as interpreted and applied, imposes a substantive requirement applicable to the same particular device that is different from, or in addition to, FDA's counterpart requirement.

(ii) FDA requirements that are applicable to devices in general, or that are established by means other than through regulation or order, should not result in preemption of State tort claims.

(12) The clearance or approval of a particular device for marketing under section 510(k), 515, or 520(g) of the act does not in itself constitute the imposition of a specific substantive requirement with respect to that particular device that preempts a State or local requirement, including a standard of care imposed under State common law, with respect to the same device.

Dated: December 8, 1997

/s/ WILLIAM B. SCHULTZ
WILLIAM B. SCHULTZ

No. 96-1405

FILED

DEC 22 1997

CLERK

IN THE

Supreme Court of the United States

OCTOBER TERM, 1996

SMITHS INDUSTRIES MEDICAL SYSTEMS, INC.,

Petitioner,

v.

SARAH KERNATS, a minor, by CYNTHIA KERNATS, her mother and next friend, CYNTHIA KERNATS, individually, and ANDREW KERNATS,

Respondents.

SMITHS INDUSTRIES MEDICAL SYSTEMS, INC.,

Petitioner,

v.

JOYCE OSHODI, individually and as mother and next friend of KENNETH OSHODI, a minor,

Respondents.

SMITHS INDUSTRIES MEDICAL SYSTEMS, INC.,

Petitioner,

v.

MARY SUSAN WILLIAMS, as mother and next friend of JOHN CALVIN WILLIAMS, a minor,

Respondents.

On Petition for Writ of Certiorari to the Appellate Court of Illinois, First District

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SUPPLEMENTAL BRIEF IN RESPONSE TO THE BRIEF OF THE UNITED STATES AS AMICUS CURIAE

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SUPPLEMENTAL BRIEF IN RESPONSE TO THE BRIEF FOR THE UNITED STATES AS AMICUS CURIAE

Petitioner, Smiths Industries Medical Systems, Inc. ("SIMS"), respectfully submits this Supplemental Brief in Response to the Brief for the United States as Amicus Curiae.

I. THE RAPIDLY GROWING CONFLICT AMONG THE LOWER COURTS REGARDING MDA PREEMPTION DEMANDS IMMEDIATE INTERVENTION BY THIS COURT.

The Government grievously understates the growing conflict among the lower courts regarding MDA preemption as it pertains to Class III PMA and IDE medical devices. Significant questions left unanswered in *Medtronic, Inc. v. Lohr* have spawned a startling proliferation of conflicting decisions by State and Federal courts. During the eight months that have elapsed since SIMS filed its Reply Brief in support of the instant Petition, numerous State and Federal courts have reached disparate results in cases involving Class III PMA and IDE devices.

The full scope of judicial conflict—which involves cases too numerous to mention here—is reflected in the charts contained in the attached Appendix. The attached charts illustrate the division of authority in cases involving Class III PMA devices (App. 1), and also in cases involving Class III IDE devices (App. 2). A third chart illustrates the significant conflict among the lower courts as to whether MDA preemption applies to "generally applicable" state law tort claims (App. 3).

The recent decision of the United States Court of Appeals for the Seventh Circuit in *Mitchell v. Collagen Corporation,* 126 F.3d 902 (7th Cir., Sept. 23, 1997), exemplifies the difficulty the lower courts have experienced in attempting to apply *Medtronic* to cases involving Class III PMA and IDE devices. In *Mitchell,* a case involving a Class III PMA medical device, the court stated that "the holding in *Medtronic* contains several ambiguities that impair our ability to perceive with absolute clarity the path that the court has chosen for us to follow." *Id.* at 910.

The sharp division among the lower courts will continue to intensify unless this Court clarifies the "several ambiguities" of the *Medtronic* holding. As stated previously, the instant Petition raises questions regarding the preemptive effect of both the IDE *and* the PMA processes. The instant Petition therefore presents an extraordinary opportunity for this Court to answer conclusively *all* of the questions that have caused the rapidly growing judicial conflict.

II. THE ILLINOIS APPELLATE COURT'S DECISION IN *KERNATS* IS A "FINAL JUDGMENT" GIVING RISE TO JURISDICTION UNDER 28 U.S.C. § 1257.

Contrary to the Government's argument, this Court has jurisdiction to review the *Kernats* decision by way of the fourth exception to the "strict finality" rule outlined in *Cox Broadcasting Corp. v. Cohn*, 420 U.S. 469 (1975). The Government contends that this case does not fall within the fourth *Cox* exception because (1) the *Kernats* decision was entered by the Illinois Appellate Court rather than the Illinois Supreme Court (Brief of the United States at 11-12), and (2) a denial of the instant Petition will not risk eroding federal policy (Brief for the United States at 12-13). The Government is wrong in both respects.

The plain language of 28 U.S.C. § 1257 permits Supreme Court review of a final judgment "rendered by the highest court of a State in which a decision *could be had*". In this case, SIMS petitioned the Illinois Supreme Court for discretionary review of the Appellate Court's decision in *Kernats*, but that petition was denied. SIMS therefore exhausted its remedies within the State Court system. As a result, the Appellate Court's decision in *Kernats* constituted the judgment of the highest court in Illinois "in which a decision *could be had*".

This Court's decision in *Organization for a Better Austin v. Keefe*, 402 U.S. 415 (1971), effectively disposes of the Government's argument. In *Keefe*, the petitioner sought this Court's review of a decision of the Illinois Appellate Court after the Illinois Supreme court denied discretionary review of that judgment. *Id.* at 417-18. Thus, the procedural posture of the case in *Keefe* was iden-

tical to this case. Significantly, this Court found jurisdiction to be present, despite the fact that the lone dissenting Justice raised the same objection to jurisdiction as the Government advances here. Id. at 422-23. This Court has similarly found jurisdiction to exist in other cases where the judgment sought to be reviewed was reviewable by a higher state court, but such review was dependent upon the court's discretion. *See, e.g., Nash v. Florida Industrial Commission*, 389 U.S. 235 (1967), and *Local 174, Teamsters Union v. Lucas Flour Co.*, 369 U.S. 95 (1962).

The Government contends that allowing Plaintiffs' tort suits to proceed will not erode the congressional goal of the MDA to protect consumers and promote public health. (Brief of the United States at 13). SIMS does not deny that one of the purposes of the MDA is to protect consumers against unsafe medical devices. However, Congress *also* enacted the MDA in order to encourage the research and development of "sophisticated, critically important medical devices" which "hold the promise of improving the health and longevity of the American people." S. Rep. No. 94-33, 94th Cong., 2d Sess. (1976), *reprinted in* U.S.Code Cong. & Admin. News 1070, 1071. Within the MDA itself, in the section applicable to Class III IDE devices, Congress announced its purpose as follows:

> It is the purpose of this subsection to encourage, to the extent consistent with the protection of the public health and safety and with ethical standards, the discovery and development of useful devices intended for human use and to that end to maintain optimum freedom for scientific investigators in their pursuit of that purpose.

21 U.S.C. § 360j(g)(1). Thus, the language of the MDA as well as its legislative history reflects a clear federal policy to encourage the advancement of medical device technology in order to serve the overriding purpose of the MDA—promoting the health of the American public.

The Government contends that the federal policy set forth above will not be jeopardized by allowing tort claims to proceed against the manufacturers of Class III PMA and IDE devices. However, the

United States Courts of Appeals, and also the American Medical Association, have taken a different position. The Sixth Circuit Court of Appeals in *Martin v. Telectronics Pacing Systems, Inc.*, 105 F.3d 1090 (6th Cir. 1997), held that allowing tort claims to proceed against the manufacturers of Class III IDE medical devices would "thwart" the "twin aims" of the IDE regulations to promote safety and innovation. *Id.* at 1099. In *Slater v. Optical Radiation Corp.*, 961 F.2d 1330, (7th Cir. 1992), the Seventh Circuit held that allowing product liability claims to proceed against an IDE device manufacturer "sets up a *direct collision with federal policy*". *Id.* at 1333. (emphasis added). And as previously stated in SIMS Petition, the American Medical Association Board of Trustees concluded in a 1988 report that product liability suits have had "a profound negative impact" on the development and availability of new medical technologies.[1]

The Government's argument that no federal policy is at risk is meritless. The federal policy underlying the MDA includes the goal of promoting public health by encouraging the development of new medical device technology. Absent the protection of MDA preemption, manufacturers of innovative medical devices may withdraw presently available devices from the market or choose not to develop new technology. As a necessary result, the health of the American public will suffer and the federal policy underlying the MDA will be eroded. Thus, the facts involved in this case fall squarely within the fourth *Cox* exception.

This Petition, for jurisdiction purposes, is also analogous to this Court's decision in *Mercantile National Bank at Dallas v. Langdeau*, 37 U.S. 555 (1963). Here, as in *Langdeau*, the judgment sought to be reviewed "is a separate and independent matter, anterior to the merits and not enmeshed in the factual and legal issues comprising the plaintiff's cause of action." 371 U.S. at 558. This is true given the fact that the issue of MDA preemption is unrelated to the merits

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[1] AMA, Report of Board of Trustees: Impact of Product Liability on the Development of New Medical Device Technologies. (June 1988).

of Plaintiffs' state law product liability claims. Furthermore, as in *Langdeau*, granting the instant Petition would serve "the policy underlying the requirement of finality in 28 U.S.C. §1257" by deciding the federal question at this time rather than subject SIMS, and Plaintiffs, to a "long and complex litigation which may all be for naught." *Id.* This is true given the fact that a reversal of the Illinois Appellate Court would preclude the need for *three separate* complex product liability actions (since this Petition involves three cases consolidated for appeal).[2]

Finding a jurisdictional basis in this case would also be consistent with this Court's prior findings of jurisdiction in cases where the federal question at issue involved the preemption of state law by federal law, and thus gave rise to important issues under the Supremacy Clause of the United States Constitution. *See, e.g., Local No. 438 Construction & General Laborers' Union v. Curry,* 371 U.S. 542 (1963); *Southland Corp. v. Keating,* 465 U.S. 1 (1984); *Mississippi Power & Light Co. v. Mississippi,* 487 U.S. 354 (1988); *Goodyear Atomic Corp. v. Miller,* 486 U.S. 174 (1988).

A final consideration warranting a finding of jurisdiction arises from the nature of the initial trial court rulings that found in favor of preemption and granted SIMS' motion for summary judgment. In each of the three cases underlying this consolidated appeal, the trial court made an express finding that its decision granting summary judgment was "final and appealable" pursuant to Illinois Supreme Court Rule 304(a). Illinois Supreme Court Rule 304(a) is the state law equivalent of Federal Rule of Civil Procedure 54(b), which permits decisions made by Federal District Courts affecting a single party in a multi-party claim to be immediately appealed. In the view of authoritative commentators, judgments made pursuant to state

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[2] All three cases have been stayed in the Circuit Court of Cook County pending the resolution of the instant Petition.

law equivalents of Rule 54(b) should be appealable to the United States Supreme Court.[3]

III. THE GOVERNMENT'S VIEW CONFLICTS WITH THE LEGISLATIVE PURPOSE OF THE MDA'S PREEMPTION PROVISION AS WELL AS THIS COURT'S DECISION IN *MEDTRONIC*.

The Government contends that the Illinois Appellate Court in *Kemats* correctly concluded that the MDA does not preempt Plaintiffs' claims. In its Petition and Reply Brief, SIMS explained the reasons why the *Kemats* decision should be reversed. SIMS will not restate those arguments here, but will address the flaws in the arguments asserted by the Government in its amicus brief.

The Government contends that the requirements imposed under the PMA and IDE processes are not sufficiently specific to trigger preemption. (Brief of United States at 14). In numerous cases decided before and after this Court's decision in *Medtronic*, the same argument has been rejected by Federal Appellate Courts and State Supreme Courts. *See e.g., Martin v. Telectronics Pacing Systems, Inc.*, 105 F.3d 1090 (6th Cir. 1997) (IDE requirements sufficiently specific); *Fry v. Allergan Medical Optics*, 695 A.2d 511 (R.I. S.Ct. 1997) (PMA requirements sufficiently specific); *King v. Collagen Corp.*, 983 F.2d 1130, 1134 (1st Cir. 1993) (PMA); *Mitchell v. Collagen Corp.*, 126 F.3d 902 (7th Cir. 1997) (PMA).

The Government contends that IDE and PMA approval of a medical device merely reflects a determination that the medical device has met certain "minimal standards for use and marketing". (Brief of United States at 14). Here, the Government understates the nature and extent of the FDA's PMA and IDE review processes. In

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[3] "If finality is achieved within a state court system by a rule [comparable to Fed.Civ.Pro. 54(b)], there is no reason to insist on a 'complete judicial unit' theory of finality. To the contrary, there is every reason to cooperate with the state attempt to achieve finality. State court review should be followed by Supreme Court review, then or never." Charles Alan Wright, Arthur R. Miller, and Edward H. Cooper, *Federal Practice and Procedure*, Chapter 10, §4010, p. 198 (2nd Ed. 1996).

Medtronic, this Court described at length the extensiveness of the PMA process, as contrasted with the cursory nature of the 510(k) premarket notification process. *Medtronic*, 116 S.Ct. at 2246-47. As set forth in SIMS' Petition, the IDE process is even more rigorous than the PMA process. (SIMS Petition at 13-14).

The approval of a medical device under the PMA process does not merely signify that device has satisfied routine administrative requirements prior to its distribution. Rather, FDA approval under the PMA process reflects a specific federal determination, made only after intense scrutiny of the device itself and of detailed information regarding its clinical use, that the device is safe and effective. 21 U.S.C. § 360e(d)(2). Approval under the IDE process reflects a similar determination regarding the safety of a particular medical device. 21 C.F.R. §812.30. The Government's characterization of PMA and IDE approval as an administrative "rubber-stamp"—made with little regard for safety and efficacy—is grossly misleading.

The Government's interpretation of MDA preemption establishes virtually unattainable requirements that effectively eviscerate the intended function of the MDA's express preemption provision. The Government contends that preemption should occur only when the FDA promulgates a regulation that (1) is specifically applicable tc a particular medical device, and (2) is separate from, and in addition to, the requirements of the PMA or IDE processes. (Brief of the United States at 15). The Government states that the FDA promulgates such regulations only in "extraordinary" circumstances. Significantly, the Government fails to identify *any* circumstance where the FDA has *ever* promulgated such a preemption-triggering regulation. Recognition of that fact raises serious doubts whether the FDA will ever promulgate a preemption-triggering regulation.

The Government also contends that preemption applies only to state law tort claims that impose "substantive requirements specifically with respect to" a particular medical device. Here, the Government seems to contemplate a state common law duty geared specifically towards a particular medical device. In reality, however,

all state law product liability claims arise from common law duties that apply to every product manufacturer. Those common law duties do not apply specifically to a particular class of devices, much less a particular medical device. Thus, the Government's interpretation of MDA preemption proposes still another requirement which, in all probability, will never be met.

Congress specifically included an express preemption provision within the MDA. Therefore, this Court must infer that Congress intended the preemption provision to actually serve a purpose. A majority of this Court's Justices in *Medtronic* held that the MDA's preemption provision should operate to preempt common claims in circumstances far less extraordinary, and far less improbable, than those described by the Government in its amicus brief. Justices O'Connor, Rehnquist, Scalia and Thomas held in *Medtronic* that certain of the Plaintiffs' manufacturing and labeling claims were preempted by the MDA. 116 S.Ct. at 2264.[4] Justice Breyer specifically rejected the statement in the plurality opinion that "few, if any, common-law duties have been preempted by" the MDA. Rather, Justice Breyer held that "I am not convinced that future incidents of MDA preemption of common-law duties will be 'few' or 'rare' ". *Id.* at 2262.

The Government's interpretation of MDA preemption essentially posits a preemption provision that will rarely, if ever, be triggered. Such an interpretation of MDA preemption cannot be reconciled with the self-evident congressional intent that the MDA preemption provision actually serve a functional purpose. Nor can the Government's position be reconciled with the opinions expressed in *Medtronic* by Justices Breyer, O'Connor, Rehnquist, Scalia and Thomas.

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[4] The holding of the aforesaid dissenting Justices is particularly significant given the fact that the medical device at issue in *Medtronic* was subject only to the 510(k) premarket notification process, not to the more rigorous PMA or IDE processes.

IV. THE FDA'S PROPOSED INTERPRETIVE RULE WILL NOT RESOLVE THE CONFLICT AMONG THE LOWER COURTS.

The Government engages in unsupported speculation by contending that the FDA's proposed "interpretive rule" will resolve the conflict among the lower courts. Although this Court held in *Medtronic* that FDA preemption regulations are entitled to "substantial weight", this Court did *not* hold that courts are bound to defer to such regulations under the *Chevron* doctrine. *Medtronic*, 116 S.Ct. at 2256; *see also*, 116 S.Ct. at 2263 (O'CONNOR, J., with whom REHNQUIST, C.J., SCALIA, J., and THOMAS, J., join, concurring in part and dissenting in part). In future MDA preemption cases, courts are therefore free to reject the FDA's proposed interpretive rule.

Prior to *Medtronic*, numerous courts rejected FDA regulation § 808.1(d)(1) as an erroneous interpretation of § 360k(a) which is contrary to Congress' intent and therefore entitled to no deference.[5] In post-*Medtronic* decisions, several courts also have reached conclusions contrary to the FDA's preemption regulations. In *Papike v. Tambrands Inc.*, 107 F.3d 737, 741-42 (9th Cir. 1997), the Ninth Circuit held that the MDA preempted a failure to warn claim arising from "generally applicable" tort principles despite the fact that § 808.1(d)(1) provides that "State or local requirements of general applicability" are not preempted. In *Mitchell v. Collagen Corp.*, 126 F.3d 902, 915 (7th Cir. 1997), the Seventh Circuit held that the MDA preempted an implied warranty claim, although § 808.1(d)(1) provides that preemption does not apply to claims based on an implied warranty of fitness.

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[5] *See, e.g., Mitchell v. Collagen Corp.*, 870 F.Supp. at 893 (N.D. Ind. 1994) (section 808.1(d)(1) is "contrary to the Congress's intent, as expressed in § 360k(a)"), *aff'd*, 67 F.3d 1268 (7th Cir. 1995), *cert. granted, judgment vacated and remanded for further consideration in light of Medtronic*, 116 S.Ct. 2576 (1996), *aff'd*, 126 F.3d 902 (7th Cir. 1997); *Talbott v. C.R. Bard, Inc.*, 865 F.Supp. at 49 (D.Mass. 1994) (section 808.1(d)(1) "conflicts with the clear expression of Congressional intent contained in 21 U.S.C. §360k(a)"), *aff'd*, 63 F.3d 25 (1st Cir. 1995).

Thus, despite the Government's hopeful expectations, the FDA's proposed interpretive rule provides scant assurance that the conflict among the lower courts will subside absent a conclusive decision issued by this Court. This is particularly true given the very real possibility that many lower courts will refuse to follow the FDA's interpretive rule based on its inherent flaws and its inconsistencies with the *Medtronic* decision.[6]

Additionally, the FDA's proposed interpretive rule will do *nothing* to remedy the division among the lower courts that exists today. In the wake of *Medtronic*, numerous Federal Appellate Courts and State Supreme Courts have reached conflicting results regarding MDA preemption. Those conflicting decisions will remain the "law of the land" regardless of the issuance of the FDA's proposed rule. Furthermore, under *stare decisis*, the subordinate Federal and State courts will be bound to follow the decisions of their "superior" courts regardless of the issuance of the FDA's proposed rule. Consequently, subordinate courts in one jurisdiction will continue to enter decisions that conflict with the decisions of subordinate courts in other jurisdictions.

The FDA's proposed rule will not resolve the current division among the lower courts. The *only* way the current conflict can be resolved is through the intervention of this Court. For if this Court were to grant the instant Petition and conclusively decide the MDA preemption issue as it pertains to Class III PMA and IDE medical devices, that decision would represent the *only* law of the land.

CONCLUSION

The petition for writ of certiorari should be granted.

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[6] The flaws and inconsistencies of the FDA's proposed rule are highlighted above in SIMS' criticism of the arguments contained in the Government's amicus brief, which arguments simply mirror the FDA's proposed rule.

Respectfully submitted,

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APPENDIX

PMA CASES	
PREEMPTION	**NO PREEMPTION**
Mitchell v. Collagen Corp., 126 F.3d 902 (7th Cir. 9/23/97)	*Lakie v. SmithKline Beecham*, 965 F.Supp. 49 (D.Columbia 3/5/97)
Fry v. Allergan Medical Optics, 695 A.2d 511 (R.I. S.Ct. 6/19/97)	*Hernandez v. Coopervision, Inc.*, 691 So.2d 639 (Fla. App. Ct. 4/18/97)
Green v. Dolsky, 685 A.2d 110 (Pa. S.Ct. 11/22/96)	*Sowell v. Bausch & Lomb, Inc.*, 230 AD.2d 77 (N.Y. App. Div. 4/10/97)
Easterling v. Cardiac Pacemakers, Inc., ___F.Supp.___ 1997 WL 732422 (E.D.La. 11/21/97)	*Armstrong v. Optical Radiation Corp.*, 57 Cal. Rptr. 2d 763 (Cal. Ct. App. 10/29/96)
Goodlin v. Medtronic, Inc., No. 97-6133-CIV (S.D.Fla. 10/29/97)	*Kernats v. Smiths Industries*, 669 N.E.2d 1300 (Ill. App. Ct. 9/3/96)
LeMay v. Eli Lilly & Co., 960 F. Supp. 183 (E.D.Wis. 4/9/97)	*Walker v. Johnson & Johnson*, 552 N.W.2d 679 (Mich. Ct. App. 7/26/96)
Steele v. Collagen Corp., 63 Cal. Rptr. 2d 879 (Cal. Ct. App. 5/15/97)	*Mears v. Marshall*, 944 P.2d 984 (Or. Ct. App. 9/10/97)
Milkiewicz v. Baxter Healthcare, 963 F. Supp. 1150 (M.D.Fla. 12/16/96)	

IDE CASES	
PREEMPTION	**NO PREEMPTION**
Chambers v. Osteonics Corp., 109 F.3d 1243 (7th Cir. 4/3/97)	*Niehoff v. Surgidev Corporation*, 95 S.W.2d (Ky. S.Ct. 6/19/97)
Martin v. Telectronics, 105 F.3d 1090 (6th Cir. 1/31/97)	*Connelly v. Iolab Corp.*, 927 S.W.2d 848 (Mo. S.Ct. 8/20/96)
Chmielewski v. Stryker Sales Corp., 966 F.Supp. 839 (D.Minn. 6/17/97)	*Baird v. American Medical Optics*, 693 A.2d 904 (N.J. App. Ct. 5/12/97)
Berish v. Smith & Nephew, 937 F. Supp. 181 (N.D.N.Y. 8/22/96)	*Shea v. Oscor Medical Corp.*, 950 F.Supp. 246 (N.D.Ill. 12/18/96)
	Kernats v. Smiths Industries, 669 N.E.2d 1300 (Ill. App. Ct. 9/3/96)

"GENERALLY APPLICABLE" STATE LAW CLAIMS	
PREEMPTED	**NOT PREEMPTED**
Mitchell v. Collagen Corp., 126 F.3d 902 (7th Cir. 9/23/97)	*Oja v. Howmedica, Inc.*, 111 F.3d 782 (10th Cir. 4/16/97)
Martin v. Telectronics, 105 F.3d 1090 (6th Cir. 1/31/97)	*Committee of Dental Amalgam Manufacturers & Distributors v. Stratton*, 92 F.3d 807 (9th Cir. 8/5/96)
Papike v. Tambrands, Inc., 107 F.3d 737 (9th Cir. 2/20/97), partially overruling *Kennedy v. Collagen Corp.*, 67 F.3d 1453 (9th Cir. 1995); conflicts with *Committee of Dental Amalgam*, (see opposite column)	*Niehoff v. Surgidev Corporation*, 95 S.W.2d 816 (Ky. S.Ct. 6/19/97)
Fry v. Allergan Medical Optics, 695 A.2d 511 (R.I. S.Ct. 6/19/97)	*Mears v. Marshall*, 944 P.2d 984 (Or. Ct. App. 1997)
Chmielewski v. Stryker Sales Corp., 966 F.Supp. 839 (D.Minn. 6/17/97)	*Headen v. Mentor Corporation*, 1997 WL 27104 (USDC E.D.Pa. 1/23/97)
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